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March 5, 2012

RECEIVED
MAR - 7 2012
Division of Biotechnology and GRAS Notice Review

Dr. Paulette Gaynor
Division of Biotechnology & GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Additive Safety & Applied Nutrition
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Corn Fiber – N-Corn Z Trim®

Dear Dr. Gaynor:

On behalf of Z Trim Holdings, Inc. of Mundelein, IL, we are submitting for FDA review the GRAS notification for Corn Fiber that is identified by the notifier as N-Corn Z Trim®. This submission reflects modifications that have been incorporated into GRN 368. Ms. Molly Harris had been involved in the coordination of the FDA review of GRN 368.

The accompanying documentation contains the specific information that addresses the safe human food uses for the subject Corn Fiber as discussed in the GRAS guidance document.

A total of four copies are provided. Some of the intended food uses include the addition of the notified substance to meat and poultry products, thereby necessitating review by USDA and the need for the fourth copy.

If additional information or clarification is needed as you and your colleagues proceed with the review, please contact me *via* telephone or email.

We look forward to your feedback.

Sincerely,

(b) (6)
[redacted]

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Robert S. McQuate, Ph.D.
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Enclosure: GRAS Notification for Corn Fiber – N-Corn Z Trim® (four copies)

GRAS ASSESSMENT

CORN FIBER - N-CORN Z TRIM®

Food Usage Conditions for General Recognition of Safety

For

Z TRIM HOLDINGS, INC.

Mundelein, IL

Evaluation By

Richard C. Kraska, Ph.D., DABT
Robert S. McQuate, Ph.D.
Madhusudan G. Soni, Ph.D., FACN, FATS

March 5, 2012

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I. GRAS EXEMPTION CLAIM

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)[1]

N-Corn Z Trim®, meeting the specifications for Z Trim Holdings, Inc. (ZTH) as described below, has been determined to be Generally Recognized As Safe (GRAS) in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. ZTH made this GRAS determination based on scientific procedures in concert with an appropriately convened panel of experts who are qualified by scientific training and experience. This finding is based on scientific procedures as described in the following sections, and the evaluation accurately reflects the conditions of the intended use of this ingredient in foods.

Signed:

(b) (6) [redacted] — March 5, 2012

Robert S. McQuate, Ph.D. — Date
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

B. Name & Address of Notifier

Z Trim Holdings, Inc.
1011 Campus Drive
Mundelein, IL 60060

As the notifier, ZTH accepts responsibility for the GRAS determination that has been made for N-Corn Z Trim® as described in the subject notification. Consequently, the N-Corn Z Trim® preparations meeting the conditions described herein are exempt from premarket approval requirements for food ingredients.

1 See 62 FR 18938 (17 April 1997) which is accessible at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083058.htm.

C. Common Name & Identity of Notified Substance

The common name of the notified substance is corn fiber or corn bran fiber.[2] The tradename for the material that is the subject of this notification is N-Corn Z Trim®.

D. Conditions of Intended Use in Food

N-Corn Z Trim® preparations are intended to be added into various food categories as a formulation aid and/or as a nutrient supplement (see Section IV.A) at per serving levels that reflect current good manufacturing practices (GMP) principles in that the quantities added to foods should not exceed the amounts reasonably required to accomplish its intended technical effect.

E. Basis for the GRAS Determination

Pursuant to 21 CFR 170.30, N-Corn Z Trim® has been determined to be GRAS on the basis of scientific procedures as discussed in the detailed description provided below. A comprehensive literature search conducted through March 6, 2012 was used in the preparation of this safety evaluation.

F. Availability of Information

The data and information that serve the basis for this GRAS notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of GRAS Associates, LLC, located at 20482 Jacklight Lane, Bend, OR 97702-3074.

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[2] Regarding the nomenclature of corn fiber and corn bran fiber, there can be some confusion from the terms used in designating these products in the published articles and the corn industry. The confusion primarily arises particularly in reference to the raw material. In the dry milling industry, corn bran refers to the pericarp. In the wet milling industry, the pericarp and some endosperm cell wall material is removed and the product is called corn fiber. The source material used in the manufacturing of N-Corn Z Trim® is obtained from the dry milling industry and is referred as corn bran. Hence, for the purposes of this GRAS assessment and in this document the raw material is referred as bran and the finished product as fiber, unless quoted material is referring to corn fiber from the wet milling industry.

II. INTRODUCTION

A. Objective

At the request of ZTH, GRAS Associates, LLC ("GA") has undertaken an independent safety evaluation of N-Corn Z Trim® for use in foods. The purpose of the evaluation is to ascertain whether or not the intended food uses of N-Corn Z Trim® can be considered to be Generally Recognized As Safe (GRAS) when used as a formulation aid and/or as a nutrient supplement in various food products.

B. Foreword

ZTH provided information on intended food uses, specifications for the manufactured material, and manufacturing information for its proprietary corn fiber which is referred to by its tradename, N-Corn Z Trim®. Determining how much N-Corn Z Trim® can be safely consumed, i.e., the so-called "dose" or use levels, is critical in the determination of safe exposure levels for N-Corn Z Trim® when consumed as a food ingredient. The composite safety/toxicity studies in concert with exposure information constitute the two critical information components that form the basis of the GRAS evaluation.

The safety/toxicity studies, consumption/exposure information, and other related documentation were augmented with an independent search of the scientific and regulatory literature through March 6, 2012. Based upon the composite information, a GRAS assessment based primarily on available safety information with corroborative information based on common occurrence in food was undertaken. Those references that were deemed pertinent to the objective at hand are listed in Section VIII.

C. FDA Regulatory Framework

Ingredients for use in foods must undergo premarket approval by FDA as food additives or, alternatively, the ingredients to be incorporated into foods must be determined to be generally recognized as safe (GRAS). The authority to make GRAS determinations is not restricted to FDA. In fact, GRAS determinations may be provided by experts who are qualified by scientific training and experience to evaluate the safety of food and food ingredients under the intended conditions of use.

In 1997, FDA altered the GRAS determination process by eliminating the formal GRAS petitioning process and replacing the petitioning process with a notification procedure. While outlining the necessary content to be considered in making a GRAS determination, FDA encouraged that such determinations should be provided to FDA in the form of a notification. However, notifying FDA of such determinations is strictly voluntary.

D. Regulatory History of Food Fibers & N-Corn Z Trim®

As early as 1882, the value of the non-starch parts of corn, including fiber, was realized. Today, many different types of corn fiber products are being produced and marketed in the US, including those noted below:

- WholeBran™ Fiber – Prairie Sky Ingredients
- Promitor® Corn Fiber – Tate & Lyle
- Vitacel® Corn Fiber – Rettenmaier & Sohne
- Hi-Maize® - National Starch

Corn bran, the portion of the corn kernel from which N-Corn Z Trim® is made, can be found in many products on the supermarket shelves, including cereals, chips and snack bars. Many corn bran ingredients used in food products are produced and marketed in the US, including:

- Stabilized Corn Bran – Bunge
- MaizeWise® Corn Bran – Cargill
- TruBran® Corn Bran – Grain Processing Corporation

Several fiber ingredients that have been recently developed/produced from other plants or grains are recognized as having GRAS status for designated food uses within the food industry. The ingredients that have successfully obtained "no questions" letters from the FDA through the GRAS notification (GRN) process are:

- Barley Fiber – Cargill Inc., **GRN 207** (FDA, 2006a)
- Carrot Fiber – Wm. Bolthouse Farms, **GRN 116** (FDA 2003 and FSIS for meat and poultry)
- Oat Hull Fiber – Grain Millers, Inc., **GRN 261** (FDA, 2009)
- Orange Pulp – Fiberstar citrus fiber, Citri-Fi, **GRN 154** (FDA, 2004)
- Potato Fiber – J. Rettenmaier USA, LP, Vitacel® **GRN 310** (FDA, 2010a)
- Oat Hull Fiber – J. Rettenmaier USA, LP, Vitacel® **GRN 342** (FDA, 2010b)
- Barley Fiber – Cargill Inc., **GRN 344** (includes meat and poultry uses) (FDA, 2011a)
- Rice Bran Fiber – CJ America Inc., **GRN 373** (FDA, 2011b)

Other fiber ingredients found in the marketplace without having undergone the FDA GRAS notification review process include:

- Pea Fiber – International Fiber Corporation (Justfiber®), Rettenmaier & Sohne (Vitacel®), Canadian Harvest/SunOpta
- Apple Fiber - Rettenmaier & Sohne (Vitacel®)
- Wheat Fiber - International Fiber Corporation (Justfiber®), Rettenmaier & Sohne (Vitacel®)
- Bamboo fiber - Rettenmaier & Sohne (Vitacel®)
- Sugar Beet Fiber – International Fiber Corporation (Justfiber®)
- Cottonseed Fiber - Rettenmaier & Sohne (Vitacel®)
- Soy Fiber – Canadian Harvest/SunOpta

III. INGREDIENT IDENTITY, CHEMICAL CHARACTERIZATION, MANUFACTURING PROCESS & PURITY

A. Chemical Identity of N-Corn Z Trim®

1. Common or Usual Name

Corn fiber and corn bran fiber are the common or usual names of the corn-derived fiber products that are the subject of the GRAS evaluation, and the specific substance that is the subject of this safety evaluation is identified by its tradename as N-Corn Z Trim® as produced and sold by ZTH. The compositional features of the subject fiber are described in more detail below.

2. Scientific Literature on Composition of Corn Bran

Corn bran is the tough fibrous outer layer or hull of the corn kernel, also known as the pericarp. Corn bran constitutes approximately 5.3% of the corn kernel. Corn bran[3] is a lignocellulosic material which is a heterogeneous complex of lignin and carbohydrate polymers (Gaspar et al., 2007). The major components of the corn bran are hemicelluloses (35%), cellulose (18%), and other starch (20%). Cellulose is a glucose polymer with a specific structure that makes it water insoluble and resistant to depolymerization. Corn bran often contains approximately 10% – 25% adherent starch in addition to the seed pericarp.

3. Carbohydrate Chemistry of Corn Bran

Corn bran contains cellulose, hemicelluloses, and lignin in a framework comprising the cell walls. The hemicellulose is a polysaccharide containing primarily arabinose and xylose (Gáspár, 2007). Lignin is a cross-linked lipophilic polymer based on phenylpropanoid units that is thought to result from the oxidative polymerization of hydroxycinnamyl alcohol precursors (Whetten and Sederoff, 1995).

Under highly alkaline conditions, lignin and hemicelluloses are removed (Gould, 1989; Anderson and Krzanarich 1935). The loss of the hemicelluloses and the lignin under alkaline conditions suggests that there are uronic ester linkages between the lignin, the hemicellulose polymers, and the cellulose (Anderson, et al., 1942; Iiyama, et al., 1994). The hemicellulosic fraction of corn fiber[3] is composed of a β-(1 → 4)-xylopyranosyl backbone and α-L-arabinofuranosyl residues as side units linked (1 → 2) or (1 → 3) to the mainchain. Side units of D-glucuronic acid or oligosaccharide side chains containing galactose, xylose and arabinose also occur (Rose, et al., 2010).

Akin and Rigsby (2008) reported that alkaline treatment of corn fiber[3] and assessment by gas chromatography revealed prevalence of ferulic acid with about 90% esters linked to cell wall. Hydrolysis of the ester linkages disrupts the integrity of the fiber, releasing the lignin and

[3] As indicated in Section I.C, this may be referred to as corn fiber as it is a product of the wet milling industry.

hemicelluloses and decreasing the crystallinity of the cellulose. This allows water to enter and hydrate the structure (Gould, 1989; Gáspár et al., 2007).

4. Composition of N-Corn Z Trim®

The basic composition of N-Corn Z Trim® is given in Table 1. The composition data are based on analytical reports on 5 commercial lots that are given in Appendices A-1 and A-2.

Table 1. Basic Composition[a] of N-Corn Z Trim®

COMPOSITION	RANGE %	METHOD
Total Dietary Fiber	87.0 - 92.0	AOAC 985.29
Cellulose	49.0 - 52.0	Calculation: Acid Detergent Fiber - Lignin
Hemi cellulose	22.5 – 37.0	Calculation: Neutral Detergent Fiber – Acid Detergent Fiber
Lignin	< 0.2	Permanganate
Starch	4.9 - 6.9	Ewers

[a] Table 1 was constructed with the fiber measurements in Appendix A-1 and the starch measurement in Appendix A-2 on 5 production batches.

B. Manufacturing Process

1. Scientific Literature on Corn Fiber Production

Corn bran is a by-product of the dry corn milling industry which has long been used in livestock feed but has the potential to be a source of dietary fiber which could be added to human foods. Some processing methods result in a product that leaves a gritty texture in the finished food product that subsequently results in degradation of the dough properties. In an attempt to overcome this issue, one solution was to grind the fiber into a fine powder. However, the powder still contained intact clusters of the cellular tissue which imparts a coarse texture in the final product. Alkaline and alkaline/peroxide treatments were also used, but such processing leaves the cellular tissue intact and again gives the final product a coarse texture. In general, these methods of preparing dietary fibers for use in foods result in food fibers with very low hydration capacity which cannot form viscous suspensions in water (Inglett, 2005). The manufacturing process used to produce N-Corn Z Trim® produces a fiber that avoids these issues.

2. Manufacturing Process for N-Corn Z-Trim®

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N-Corn Z Trim® is a multifunctional fiber ingredient made from the pericarp (bran) of the corn kernel. It has its origin in a USDA patent for the unique processing of agricultural raw materials (Inglett, 2005). The product is not bleached. The invention deals with the conversion of by-products such as bran and hulls to dietary fiber gels for use in the preparation of calorie-reduced foods, among others. The basic process outlined in the patent centers on the disintegration of the cellular structures of the dietary fiber substrates which is carried out in a multistage process in the presence of alkali. The resulting slurry is cleanly separated into solids and liquids, and the solids are recovered as a gel product. The gels may then be dried to yield a rehydratable flake or powder (Inglett, 2005).

N-Corn Z Trim® is made from the bran of the corn kernel which constitutes approximately 5% of the corn kernel. It is manufactured under food grade conditions as outlined in Figure 1, including the application of accepted GMP and HACCP practices. N-Corn Z Trim® is an unbleached product to retain its natural color. The bran is rehydrated using hot water. The resulting slurry is then tested for percentage of solids and pH. If required, the pH is adjusted with NaOH to a range of 5 to 6. A starch hydrolysis step follows. NaOH is again added to the alkali steeping process and allowed to react until a designated viscosity is obtained. A washing stage then follows and involves the intermittent addition and removal of hot wash water. The color, percentage of solids, and pH are recorded, and when they have reached the product specifications, washing stages are stopped. Tocopherol and lecithin are added to the suspension. Citric acid may be used to ensure that the proper pH of 6 to7 is reached. The color, percentage of solids, and pH are again determined and recorded. The suspension is then dried with additional lecithin being used if needed to optimize drying. Moisture is recorded for the dried product, which is then milled to pass through a 20 mesh screen. A set of magnet traps is used to ensure that no contamination occurs with potential metal fragments. The moisture in the final product is tested to ensure that it is within product specification.

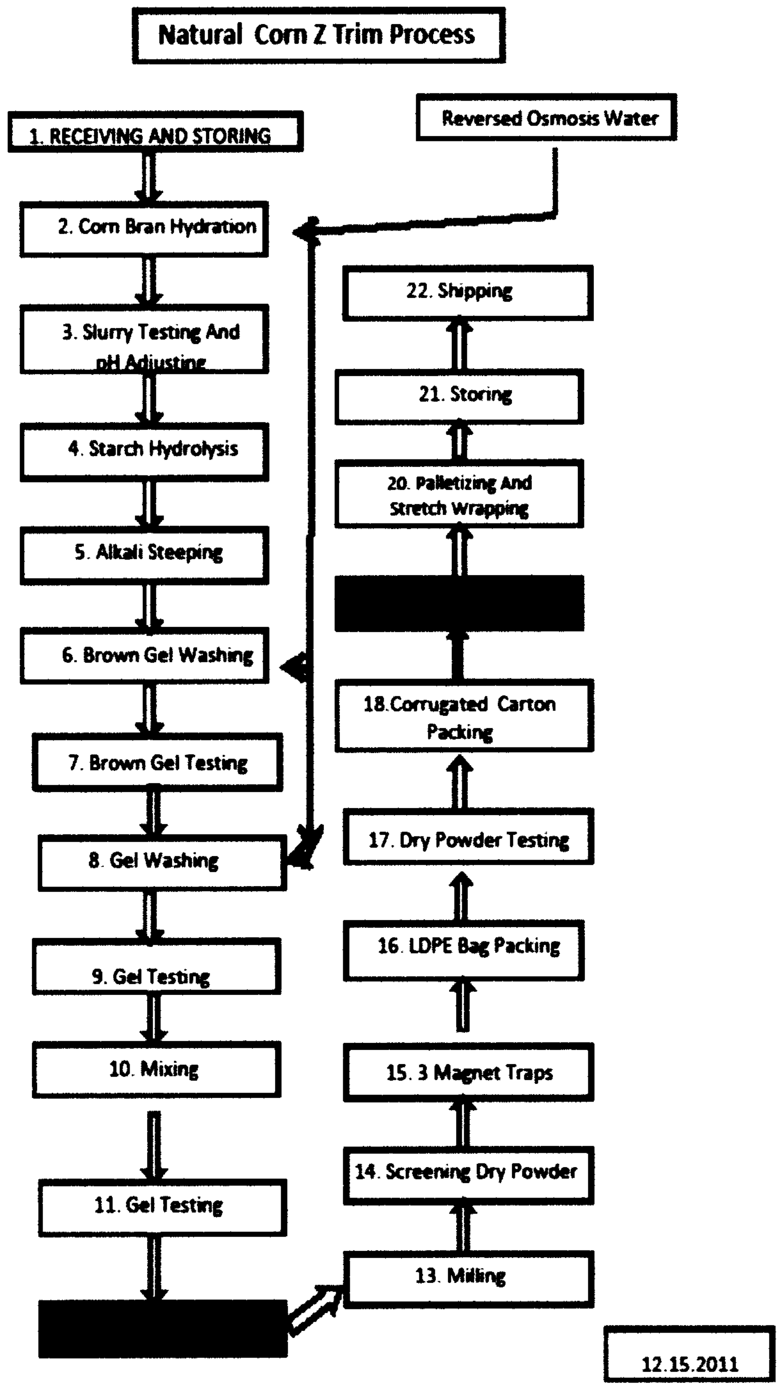
3. Quality Control of Manufacturing Process

The plant where N-Corn Z Trim® is produced is a HACCP-designed facility, which has a HACCP plan specifically designed for the N-Corn Z Trim® powder manufacturing process. ZTH has standardized product recall, internal quality audit, cleaning and sanitation, finished product label control, allergen policy, and microbiological and environmental programs, as well as a Supplier Approval Policy. In addition, Standard Operating Procedures for all equipment which include regular maintenance and cleaning requirements have been instituted. An audit for compliance with Good Manufacturing Practices and Food Safety Systems was performed in December 2011 by Silliker® Food Safety and Quality Systems of Homewood, IL. ZTH achieved an overall score of 98.6% during this audit, demonstrating that ZTH met a very high standard of excellence.

4. Quality Control of Finished Product

The safety and quality of the final product is ensured in a number of ways. The ingredients used in the manufacture of N-Corn Z Trim® all have FDA GRAS or food additive citations, and they come with Certificates of Analysis from the suppliers that document compliance with Food Chemicals Codex (7th Edition) specifications. Although 21 CFR 184.1400 does not specifically mention use of sunflower lecithin sources, the lecithin used by ZTH complies with FCC (7th Edition) specifications and is considered to be safe and GRAS by the Expert Panel for its intended use. The final product is tested, and certificates of analysis are prepared which adhere to the specifications contained in Table 2. In addition, batches have been tested for microbial contamination, organophosphate, and organochlorine pesticides as well as polychlorinated biphenyls and mycotoxins as outlined in Table 3.

Figure 1. Flow Chart for the Manufacture of N-Corn Z Trim®



C. Product Specifications

1. General Physical Properties

N-Corn Z Trim® is an off-white powder containing brown specks that has a neutral taste and odor. It is primarily an insoluble fiber which has the ability to absorb more than 20 times its weight in water. This characteristic imparts many functional properties to the finished food products, such as texture improvement, binding, moisture management, fat replacement, and yield extension.

2. Physical/Chemical Specifications

The physical properties and specifications for N-Corn Z Trim® are compiled in Table 2. A summary of analyses demonstrating that 5 production batches of N-Corn Z Trim® meet the physical and microbiological specifications is provided in Appendix A-3. Certificates of Analysis for these five batches are included in Appendix A-4. External reports referred to in Appendix A-3 are provided as Appendices A-1 and A-2. An additional nutritional analysis including a fatty acid profile on a composite sample of five batches is included as Appendix A-5. Finally, Appendix A-6 is a mineral screen on a composite sample of five batches. Variations in the levels of sodium from the batch analysis data reflect to the use of sodium hydroxide in the processing. The levels of sodium ranged from 193 to 1110 mg/100 g. Among the five batches analyzed, in three batches sodium levels were below 400 mg/100g while in the remaining two batches it was 682 and 1110 mg/100 g.

3. Nutrition Content

N-Corn Z Trim® is an insoluble fiber that can function as a fat replacement. Nutritional analyses of N-Corn Z Trim® are given in Table 4. This is based on a composite nutritional analysis of 5 lots provided in Appendix A-5. As the specifications have been well established and in order to minimize the expenses, nutritional analyses from a composite batch of 5 lots have been performed. Additionally, Appendix A-2 provides nutritional analysis data for fat, protein, calcium and iron from five independent batches.

4. Contaminants

The levels for possible contaminants for N-Corn Z Trim® are listed in Table 3. For contaminants such as heavy metals, pesticides and mycotoxins, the levels noted were below detection limits. Pesticide analyses for 5 lots are found in Appendix A-1. Aflatoxin and vomitoxin measurements are also listed in Appendix A-1. In addition to these two mycotoxins, fumonsin was measured from two batches of raw material and one composite batch consisting of 5 batches of N-Corn Z Trim®, and the levels were found to be <1 ppm. The collection of these reports, along with reports for heavy metals (also presented in Appendix A-1), and microbial contaminations (Appendix A-4) demonstrate that the product is well characterized and meets the purity criteria.

Table 2. N-Corn Z Trim® Physical Properties & Specifications

Organoleptic Properties	**Description**
Physical form	Powder
Color	Off-white containing brown specks
Flavor	Odorless
Odor	Tasteless
Physical Data	**Specification Range**
Easily dispersible powder	
Color L Value	L > 82.00 a = -0.80 – 3.00, b = 8.00 -18.00
Viscosity	20000 – 40000 cps, Temp at 21.0 – 41.0 °C, 4.00% solids
Chemical Composition	
Moisture, %	8.00 Max
Ash, %	Less than 3.5
Total Dietary Fiber, %	87.00 - 92.00
Metals	
Arsenic, ppm	< 0.2
Cadmium, ppm	< 0.2
Lead, ppm	< 0.2
Mercury, ppm	< 0.2
Sodium, mg/100 g	<1500
Microbiological Data	
Aerobic Plate Count (TPC)	<1000 cfu/g
Coliform (MPN)	<10 cfu/g
Yeast & Mold (PDA count)	<100 cfu/g
E. coli	<10 cfu/g
Salmonella	Negative[a]/ 25 g

[a] Salmonella testing is qualitative, meaning absence or presence.

D. Stability Data

In a series of tests, the stability of a bleached version of Corn Z Trim® was investigated. The results of these tests are provided in Appendix A-7. Representative samples meeting standard specifications were placed in sealed plastic bags and stored at ambient temperature for 6, 12, 18, 24, and 30 months. The stored samples were tested at the end of each time period for sensory, color, viscosity, granulation, moisture, and microbiological characteristics. The results for sensory, color, viscosity, and granulation tests demonstrate that Corn Z Trim® continued to conform to product specifications after storage at all time periods through 30 months. In a small number of samples, moisture levels rose above the specification maximum due to the nature of the packaging of the samples. However, water activity remained under 0.5% and is unlikely to support microbial proliferation even after 30 months of proper handling and storage.

Table 3. Contaminant Analyses of N-Corn Z-Trim®

Organophosphate Pesticides		
Pesticide	**Results**	**Method**
Diazinon	< 0.0200 ppm	AOAC 970.52
Disulfoton	< 0.0200 ppm	AOAC 970.52
Ethion	< 0.0200 ppm	AOAC 970.52
Malathion	< 0.0200 ppm	AOAC 970.52
Methyl Parathion	< 0.0200 ppm	AOAC 970.52
Parathion	< 0.0200 ppm	AOAC 970.52
Thimet	< 0.0200 ppm	AOAC 970.52
Thiodan	< 0.0200 ppm	AOAC 970.52
Trithion	< 0.0200 ppm	AOAC 970.52
Organochlorine Pesticides & PCBs		
Pesticide	**Results**	**Method**
Heptachlor Epoxide	< 0.0200 ppm	AOAC 970.52
Heptachlor	< 0.0200 ppm	AOAC 970.52
DDE	< 0.0200 ppm	AOAC 970.52
Lindane	< 0.0200 ppm	AOAC 970.52
Endrin	< 0.0200 ppm	AOAC 970.52
Mirex	< 0.0200 ppm	AOAC 970.52
Alpha-BHC	< 0.0200 ppm	AOAC 970.52
Delta-BHC	< 0.0200 ppm	AOAC 970.52
Aldrin	< 0.0200 ppm	AOAC 970.52
Dieldrin	< 0.0200 ppm	AOAC 970.52
DDT	< 0.0200 ppm	AOAC 970.52
Chlordane	< 0.0200 ppm	AOAC 970.52
Methoxychlor	< 0.0200 ppm	AOAC 970.52
Beta-BHC	< 0.0200 ppm	AOAC 970.52
HCP	< 0.0200 ppm	AOAC 970.52
PCB	< 0.1500 ppm	AOAC 970.52
Mycotoxins		
Toxin	**Corn Fiber (Finished) Results**	**Method**
Aflatoxins	<10 ppb	ELISA
Vomitoxin	<1 ppm	ELISA
Fumonisin	< 1 ppm	NPAL-FUMO

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Table 4. Nutritional Analyses of N-Corn Z Trim®

ANALYTE	VALUE/100G	UNITS	CALORIES PER GRAM	CONTRIBUTION TO CALORIES
Fat	0.32		9	2.9
Sodium	570	mg		
Total Carbohydrates	93.4	g		
Total dietary Fiber	91.67	g		
Soluble Fiber	3.59	g	4	14.3
Insoluble Fiber	88.07	g	0	0
Total Sugars	< 0.25	g	4	1.0
Fructose	< 0.25	g		
Glucose	< 0.25	g		
Sucrose	< 0.25	g		
Maltose	< 0.25	g		
Lactose	< 0.25	g		
Protein	< 0.1	g	4	0.4
Calories/100g (calculated)[a]				18.6

[a] Note that the calories calculated in Appendix A-5 is in error because it incorrectly assumes the non-fat and non-protein fraction of the product is digestible carbohydrate.

The above described product stability was investigated with bleached version of Corn Z Trim® that has specifications equivalent to the subject product, i.e., N-Corn Z Trim®. Given the similarity in specifications, it is unlikely that there will be any significant differences in the stability between bleached version and the current unbleached product. The bleaching process is known to remove the light yellow color caused by xanthophylls and is unlikely to significantly affect the product stability. Hence, the stability results as discussed above from bleached version of Corn Z Trim® are applicable to the subject of the present GRAS assessment. Additionally, ZTH has analyzed a composite sample of N-Corn Z Trim® that was stored for 6 months for microbiological markers, and the results comply with the standard specifications. Results of the testing on this sample are provided as Appendix A-8.

IV. INTENDED USES & DIETARY EXPOSURE

A. Intended Uses

N-Corn Z Trim® has undergone extensive product development testing in a variety of food products, and use levels have been established which maintain the sensory properties expected of the finished food products. N-Corn Z Trim® is intended to be used as a formulation aid as defined in 21 CFR 170.3(o)(14) and/or as a nutrient supplement as defined in 21 CFR 170.3(o)(20) for incorporation in baked goods, breading and coatings, dairy products, egg products, meat and poultry products, dressings, dips, soups, gravies, sauces, snacks, fillings, toppings, and icings.

The use levels of N-Corn Z Trim® will usually fall in the range of 0.75% to 2.0%, although for some applications and functionalities the use levels can be as low as 0.01% and as high as 3.0%.The intended food uses, technical effects in foods, and use level ranges are presented in Table 5.

B. Dietary Exposure

Based on the intended food uses of N-Corn Z Trim®, a point estimate for dietary intake was calculated using FDA guidelines (FDA, 2006b). USDA survey data were used to estimate mean per capita levels of consumption from the chosen food categories. Based on the use of the FDA guidelines and USDA survey data, a level of twice the mean was calculated as an overestimate for the 90th percentile total consumption of these foods. This estimate indicates that a high consumer of foods containing N-Corn Z Trim® powder is likely to consume 27.0 g/person/day as shown in Table 6. Compositional analyses of N-Corn Z Trim® suggest that the product contains 92% fiber as reported in Table 4. Hence, the fiber intake from the intended uses of N-Corn Z Trim® would be 24.8 g/person/day.

The actual intake of N-Corn Z Trim® is expected to be lower than the estimated intake. First, it is anticipated that the average consumer will consume N-Corn Z Trim®, in some, but not all, of their daily fiber-based food selections. Secondly, the estimated daily intake is for the highest proposed use levels for that particular food category, while for a majority of food categories a range of use levels is proposed, and the likely total intake is expected to be low. Additionally, some of the food categories---such as coatings and breadings listed in the estimated daily intake---are grossly overestimated since the "all grain" category is used in the estimates. As indicated in the 2006 FDA guidance, these calculated values of N-Corn Z Trim® powder should be viewed as overestimates of the 90th percentile consumption. The estimated intake is based on levels of consumption that comply with dietary fiber source claims (e.g., high source and very high source) which are considered to be safe as little to no adverse effects have been observed or reported.

Based on the specification of 1500 mg of sodium in 100 g of N-Corn Z Trim®, the maximum expected sodium intake from 27.0 g would be approximately 400 mg per person per day.

C. Use in Products Under USDA Jurisdiction

In accordance with the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act, the Food Safety and Inspection Service (FSIS) of USDA is responsible for determining the efficacy and suitability of food ingredients in meat, poultry, and egg products as well as prescribing safe conditions of use. As part of a requirement by USDA on the uses of a new food ingredient in meat and poultry products, the effects of a bleached prototype of Corn Z Trim® addition to ground and processed meat products on consumer acceptability were investigated. As indicated earlier, the natural product, N-Corn Z Trim®, is not expected to differ in performance and efficacy compared to the bleached product in meat/poultry. The details of these studies are presented in Appendix B.

Table 5. Intended Food Uses & Use Levels

INTENDED FOOD CATEGORIES	TECHNICAL FUNCTIONS	TYPICAL USE LEVELS(%)
BAKED GOODS & CEREAL PRODUCTS doughs, batters, mixes, baked goods (muffins, biscuits, cookies, cake, tortillas etc.)	Improve Texture Retain Moisture Replace Fat Improve Freeze-Thaw Stability	0.25 - 1.75
COATINGS & BREADINGS for meat, poultry & vegetables	Improve Texture	1.0 - 3.0
DAIRY PRODUCTS milk products, yogurts, sour cream, cheeses, ice creams, spreads, etc.	Control Syneresis Provide Texture Replace Fat Manage Moisture	1.0 – 1.5
EGG PRODUCTS omelets, frittatas	Improve Texture Manage Moisture	0.50 – 1.5
MEAT , POULTRY & SEA FOOD ground, whole muscle, emulsified, processed meats	Improve Texture	0.30 - 2.0
DRESSINGS & DIPS	Replace Oils/Fats Improve Texture Stabilize Emulsion	0.5 – 3.0
SAUCES, SOUPS & GRAVIES	Control Syneresis Improve Texture Stabilize Emulsion Replace Fat Replace Starches	1.5 – 3.0
SNACKS salty snacks, nutrition bars	Improve Texture Binder	0.5 - 1.50
FILLINGS, TOPPINGS & ICINGS	Manage Moisture Improve Texture Replace Starches Replace Fat	0.5 – 3.0

Table 6. Estimated Daily Intake[a]

Food Category	USDA Category	Use Level grams per 100 grams (Percent by Weight)	USDA Mean Grams of Food Consumed	Mean Additive Consumed (g/day)	Mean x 2 Additive Consumed (g/day)	Data Table, Page Number
Baked Goods, & Cereal Products	Quick breads,Tortillas, pancakes, French Toast	1.75	19	0.333	0.665	26
	Yeast breads and rolls	1.75	50	0.875	1.750	26
	Cakes, cookies, pastries, pie	1.75	38	0.665	1.330	26
	Pasta	1.75	18	0.315	0.630	26
Coatings & Breading	Mixtures mainly grain	3.0	109	4.360	8.720	26
Dairy Products	Milk and milk products	1.5	274	4.11	8.22	29
Egg Products	Eggs	1.5	18	0.270	0.540	31
Meat, Poultry & Seafood	Beef	2.0	24	0.480	0.960	30
	Pork	2.0	10	0.200	0.400	30
	Lamb, Veal, Game	2.0	1	0.020	0.040	30
	Organ Meats	2.0	1	0.020	0.040	30
	Frankfurters, sausages, luncheon meats	2.0	21	0.420	0.840	30
	Poultry	2.0	25	0.500	1.000	30
	Fish and Shellfish	2.0	10	0.200	0.400	30
Dressings & Dips	Salad Dressings	3.0	8	0.240	0.480	31
Sauces, Soups & Gravies[b]		3.0	46.8[b]	1.404	2.808	
Snacks	Crackers, popcorn, pretzels, corn chips	1.5	12	0.180	0.360	26
Fillings, Toppings & Icings	Sugars and Sweets	3.0	7	0.210	0.420	31
Total				13.502	27.003	

[a] DATA TABLES: Results from the USDA's 1994-96 Continuing Survey of Food Intakes by Individuals and1994-96 Diet and Health Knowledge Survey Table Set 10 Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, U.S. Department of Agriculture, 10300 Baltimore Ave.,Bldg. 005, Rm 102, BARC-West, Beltsville, Maryland 20705-2350; see http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm.

[b] Since data for these categories from USDA surveys were not available, MRCA (1965) data for daily consumption of gravies (8.3 g), soups (31.7 g) and sweet sauce (6.8 g) were used.

In these experiments, ground meat (beef, turkey) and processed meat (frankfurters) were prepared by adding hydrated (10%) Corn Z Trim®. The hydrated product used was formed from 90% water and 10% Corn Z Trim®. For test purposes, the level of Corn Z Trim® in the meat and poultry product ranged from 0.13% to 2%. The proposed maximum use for N-Corn Z Trim® in meat and poultry products is up to 2.0% (see Table 6). The prepared products were tested for yield (weight), instrumental texture (TA.T2X analyzer), and sensory attributes (human panelists). Changes in texture were measured for hardness, springiness, cohesiveness, gumminess, and chewiness. Regarding sensory attributes, highly trained human panelists tested burger patties for: hardness, chewiness, cohesiveness, moisture release, and oily mouth coating; and the frankfurters were evaluated for: springiness, overall hardness, chewiness, cohesiveness of mass, grainy texture, and oily mouth coating. The findings from these analyses are briefly described below:

Yield: Except for a slight increase in hamburger yield over control when fat was removed and Corn Z Trim® was added as a binder, no other changes in any of the products were noted.

Texture: The tenderness of most burger formulations containing Corn Z Trim® did not significantly differ from that of the control. The exceptions were the burgers containing the maximum amounts of Corn Z Trim® studied. Hamburgers and turkey burgers with 2% and 1.3% Corn Z Trim®, respectively, were measured to be "more tender" than the control. This difference may be attributed in part to the lower meat (i.e., beef fat or turkey skin) levels of the treatments. For processed meat (frankfurter), Corn Z Trim® formulations were significantly different except in springiness. The utility of these instrumental measurements for quality control purposes are unquestioned. However, the instrumental measurements for frankfurters often do not correlate well with sensory scores.

Sensory Attributes: Except for hardness in hamburger, trained panelists could not differentiate Corn Z Trim® treated burgers from the control. Beef burgers with Corn Z Trim® were slightly "more tender" than the control. Similar results were noted for processed meat (frankfurter). The difference detected in beef and not in turkey burgers partly corresponded with observed instrumental measures discussed above. Generally, more tender patties and frankfurters may be considered desirable if other texture characteristics remain the same.

In summary, the results of these investigations revealed that the addition of Corn Z Trim® to meat and poultry products does not alter the acceptability of the prepared products as evidenced by texture analysis and sensory attributes.

V. N-CORN Z TRIM® SAFETY INFORMATION

A. Historical & Modern Day Dietary Uses of Corn & Corn Bran in Foods

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Corn has been consumed in the US for centuries. It is believed that corn was originally cultivated in the Andes of South America, and from there it was introduced into Central America and then into Mexico where it was grown by the Mayan and Aztec tribes. There is evidence that corn plants were hybridized and domesticated between 10,000 and 5,500 BC but did not find their way to the US until around 600 AD when a number of North American Indian tribes were growing it for food.

Corn use spread across the Americas well before their discovery by Columbus in 1492. He received it as a gift from the Natives and took it back to Spain where its cultivation subsequently spread throughout Europe and the rest of the World. ZTH research reports that approximately 35.2 million metric tons of corn were used in food in 2007, which equates to an estimated annual per capita consumption of 250.7 pounds.

Many types of processed food ingredients are made from corn. Corn refining started when the first dedicated starch plant in the world opened in New Jersey in 1844. Subsequently, other products from corn followed, including dextrose in 1866, refined cornstarch in 1882, thin boiling starches in 1900, maltodextrin and low DE syrups in the mid-1950s and HFCS-42 in 1968. As early as 1882 the value of the non-starch parts of corn, including fiber, was being realized.

A variety of definitions of dietary fiber exists. In 2001 the Food and Nutrition Board of the Institute of Medicine assembled a panel to develop a proposed definition of fiber. The definition they proposed consisted of the following: "dietary fiber consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants" (IOM, 2005). The definition of dietary fiber was also reviewed by the American Association of Cereal Chemist (AACC, 2001) in 1998 to 2001. Their definition appears below.

> "Dietary fiber is the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin and associated plant substances. Dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation" (AACC, 2001).

Current belief is that consumption of a diet high in fiber is associated with a lower incidence of some disorders or diseases. Insoluble fiber is required in the human diet to maintain colonic function and to reduce the incidence of constipation (Stephen et al., 1997). Insoluble fibers usually have a high water-holding capacity, which enables it to increase the fecal bulk. Given the importance of dietary fiber in human health, the FDA allowed two health claims for products containing fiber. The producers of foods containing 0.75g of oat or barley soluble fiber as beta-glucans or 1.7g/serving of psyllium husk soluble fiber can claim that regular consumption of these products can reduce risk of heart disease. The continuation of recommendations regarding dietary fiber from government and other organizations as well as the production of study reports by the scientific community have ensured that dietary fiber discussions continue today. Currently, companies are required to put information regarding the fiber content on food labels in the US and are allowed to make specified health claims on the labels.

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Dietary fiber in the human diet is available from many sources according to the US Department of Health and Human Services USDHHS/USDA (2010) and as found in the 2010 Dietary Guidelines for Americans. It is recommended that all adults eat half their grains as whole grains. The USDA and HHS recommend that the daily intake of dietary fiber should be 14 grams per 1000 calories, which equates to 22 – 34 grams per day for a normal adult diet (USHHS/USDA, 2010). The Institute of Medicine (IOM) recommends a daily intake of 25 and 38 grams of dietary fiber per day for adult women and men < 50 years of age, respectively (IOM, 2005). For adults > 50 years of age, the recommended daily dietary fiber level is 21 grams for women and 30 grams for men. Whole grain foods must contain the entire grain seed or kernel. The kernel is made up of the bran, germ and endosperm. In the grain refining process the majority of the bran and germ is removed which results in a loss of the dietary fiber in foods made from refined grains.

It is well recognized that whole grain wheat, oats and other cereal grains provide much of the fiber added to processed foods. Corn bran is present in many products available to consumers in the US such as cereals, chips and snack bars. Corn fiber products are already being produced and marketed in the US. Additionally, many corn bran ingredients for use in food products are also currently produced and marketed in the US. There is much consumer and food industry interest in having foods that are enriched in fiber content. In GRN 261 (FDA, 2009), Grain Millers, Inc. established that its Oat Fiber for use as an ingredient in food is GRAS. In GRN 154 (FDA, 2004), citrus fiber from orange pulp cells (Cirti-Fi™ Fiberstar, Inc.) was established to be GRAS for use in foods. Wm. Bolthouse Farms demonstrated that the use of carrot fiber as a texturizer in foods was GRAS in GRN 116 (FDA, 2003). In GRN 207 (FDA, 2006a) and GRN 344 (FDA, 2011a), Cargill Inc. concluded that barley fiber is GRAS for use in several food categories. J. Rettenmaier USA concluded that two Vitacel® products---potato fiber (GRN 310) and oat fiber (GRN 342)---are GRAS (FDA, 2010a and 2010b). Recently, CJ America Inc., in GRN 373(FDA, 2011b) has determined that Rice Bran Fiber is GRAS for use in several food categories. In all these GRAS notifications, the safety affirmations were based on scientific procedures and were justified by comparing the chemical compositions to natural fiber from these sources while extending the comparison of dietary intake between the fibers from each particular food source to the estimated consumption of fiber ingredient in the proposed uses. Only Cargill performed any toxicology studies.

B. Fermentation of Dietary Fiber

In recent years, much of the interest in dietary fiber and its effects in humans has focused on its fermentation in the colon. Fermentation of fiber in the colon is known to produce short-chain fatty acids (SCFA) and gases (CO_2, CH_4 and H_2) (IOM, 2005). The extent to which fiber is fermented affects its physiological effects in humans. Following absorption, each of the primary SCFA produced (i.e., acetate, propionate and butyrate) is metabolized differently by the body. Butyrate is a preferred energy source for colonocytes and thus is extensively metabolized by the colon. Propionate is utilized primarily by the liver and has been suggested as a potential modulator of cholesterol synthesis. Acetate largely by-passes colonic and liver metabolism but is metabolized by peripheral tissues (i.e., muscle). Unfermented fiber residues and associated water increase fecal mass and may be protective against ailments such as colon cancer and diverticulosis (Bourquin et al., 1992). The colonic effects of extensively fermentable fiber sources are related to end-products of fermentation, whereas the colonic effects of poorly fermented fibers depend more on the physical properties (i.e., water-holding capacity) of the fiber itself. Numerous studies have been conducted on fiber fermentation by humans both *in vivo* and *in vitro*.

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Corn bran has been reported to be relatively refractory to degradation by human fecal bacteria. Corn bran is poorly fermented as it produces less SCFA compared to other fibers such as gum arabic, a mixture of arabic-guar, and apple pectin (Titgemeyer et al., 1991). In an *in vitro* study, Bourquin et al. (1992) investigated degradation of corn fiber, oat bran and wheat bran, and SCFA production by human colonic bacteria. Total dietary fiber concentration of corn fiber was 63.3 g/100 g of dry matter. Fiber was inoculated with feces from three human volunteers for 6, 12, 18, 24 and 48 hours. For corn fiber, the substrate dry matter remaining after 48 hours of fermentation was 87.8% for total dietary fiber fractions. The average production of the short-chain fatty acids, acetate, propionate and butyrate, across all treatments occurred in the molar ratio of 63:21:16, respectively. However, profiles of short-chain fatty acids produced were influenced by both treatment and inoculum source. The extent of substrate fermentation varied among inoculum donors, suggesting that colonic microbial activities differ among individuals.

C. Toxicology Studies Relevant to Corn Fiber

The fundamental safety considerations of these fibers have been generally recognized by scientists over a sustained period of time and are not in question; therefore, traditional toxicity studies in laboratory animals were not systematically conducted to support fiber uses in human foods. Moreover, dietary fiber is an important component of the food for laboratory animals. For instance, Purina indicates that its certified rodent chow consists of 4.5% dietary fiber.[4] So the presumption is that fiber is both a harmless and beneficial nutrient at these levels in these laboratory animals. Moreover, animal testing to study the toxicology of a fiber source at varying dietary levels would possibly cause nutritional imbalances depending on the animal model.

There are studies in the literature where corn fiber or corn bran was fed to animals; however, it is important to note that the focus of these studies was to determine the health effects of feeding corn fiber to animals and not safety endpoints. In one study, the effect of particle size of corn bran on the plasma cholesterol concentration, fecal output, and cecal fermentation in rats was studied (Ebihara and Nakamoto, 2001). Rats were fed either a fiber-free diet or the same diet supplemented with corn bran at six different particle sizes for 21 days. As the particle size decreased, the plasma cholesterol concentration, fecal wet weight, and fecal bulking effect decreased, while the liver cholesterol concentration, cecal wall weight, wet weight of cecal content, and total organic acids, acetic acid and n-butyric acid in the cecal content increased.

In another study, rats were fed a diet containing 10% corn bran dietary fiber for 4 weeks to study the effect on the expression of several genes involved in lipid metabolism (Hu, 2008). No adverse effects were reported in these studies. There are three studies in which corn bran was fed to finishing steers, and no adverse effects were reported (Nebraska, 1997, 2002, 2005). Zhao et al. (2005) fed a diet containing 5% refined corn bran to rats to evaluate the bioavailability of phenolic antioxidants, ferulic acid (FA), and *p*-coumaric acid (PCA) present in the refined corn bran. Rats were fed a single meal or were adapted to the diet for 10 days. The recovery of the antioxidants was determined in plasma, urine and feces. The results showed that the phenolic acids in refined corn bran are bioavailable in rats but at a relatively low level compared with the high content in the diet. No adverse effects following consumption of the refined corn bran diets were noted in the study. There was no difference in food intake, body weight gain or eviscerated carcass weight compared to controls. From these studies, the consumption of corn fiber/bran is presumed to be safe for animals.

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[4] See http://labdiet.com/pdf/2008%20LabDiet%20Technical%20Update.pdf.

D. Clinical Studies on N-Corn Z Trim® & Other Relevant Corn-Based Materials

Clinical studies are important to demonstrate that the subject fiber sources provide dietary fiber that can be tolerated by humans when ingested at expected levels without triggering digestive problems or other undesirable effects. One clinical study on Corn Z Trim® and six other studies on other preparations of corn fiber support the safety of the ingredient.

Hallfrisch et al., (2002) studied the glucose and insulin responses to the consumption of Z Trim® from grains, including corn, in humans. The objective of this study was to determine the effects of the consumption of various doses of this new fiber on glucose and insulin responses in humans. The twenty four male and female volunteers (equal numbers of male and female subjects) in this study were matched for age and body mass index which were 41 and 27 years, respectively. The volunteers were given glucose or glucose with three levels of fiber in a Latin square design. The levels of Z Trim® used in the study were 0.08, 0.17 and 0.33 g/kg body weight. The volunteers consumed control diets for three days during each of the four experimental periods. The diets were identical for all volunteers and were prepared at the Beltsville Human Nutrition Research Center Human Study Facility. Blood samples were collected before and at 30, 60, 120, and 180 minutes after the solutions containing glucose or glucose and fiber were consumed. The plasma glucose, insulin, and glucagon levels were determined using enzyme assay or radioimmunoassay methods. The results showed that the decline in glucagon, which normally occurs following glucose ingestion, was moderated by the addition of insoluble fiber; however, it appears to be less effective than soluble fiber. The volunteers reported few adverse gastrointestinal symptoms. The symptoms in the males included 11 reports of feeling too full prior to consumption of the Z Trim® but only one report of feeling too full after the consumption of Z Trim®. In the females, there were three reports of feeling too full prior to the consumption of the Z Trim® and three reports of feeling too full after the consumption of the Z Trim®. Diarrhea was reported in one man after consumption of the low level of Z Trim® and in one woman after consumption of the high level of Z Trim®. The most reported gastrointestinal symptom was flatulence. In men, there were 11 reports of flatulence prior to the consumption of Z Trim® and three reports after consumption of Z Trim®. In the women there were three reports of flatulence prior to the consumption of Z Trim® and two reports after the consumption of Z Trim®. Nausea was reported by one man and one woman following the consumption of the high level of Z Trim®. The authors concluded that since many of the symptoms appeared prior to the consumption of the Z Trim®, these gastrointestinal symptoms were likely the result of a higher consumption of fiber than was usual for the subjects.

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In another study, human volunteers were asked to consume muffins which contained either high or low fiber (Willis et al., 2009). Four kinds of high fiber muffins were included in the study (corn bran, barley β-glucan with oat fiber, resistant starch, and polydextrose), and one low fiber muffin was included. Healthy volunteers (n=20) were recruited and were between 18 and 65 years of age with a body mass index of less than 30. The study was designed as a randomized, double-blind, crossover study to compare the effects of the treatment on satiety. Subjects were asked to consume either a low-fiber muffin or one of the four high-fiber muffins in 5 separate visits which were one week apart. Fasting subjects consumed either a low fiber muffin (1.6 g fiber) or 1 of 4 high-fiber muffins (8.0-9.6 g fiber) for breakfast. Subjects answered 4 questions on 100 mm visual analog scales to rate baseline satiety, prior to muffin consumption, as well as satiety at 15, 30, 45, 60, 120 and 180 minutes after muffin consumption. The results showed that not all fibers affect satiety to the same degree, with resistant starch and corn bran having the most effect on satiety. No adverse effects following corn bran consumption were reported during the study.

Shane and Walker (1995) studied the lipid-lowering effects of corn bran when taken in moderate supplemental doses by men with hypercholesterolemia who were consuming a low fat diet. Twenty nine men with a sedentary lifestyle and hypercholesterolemia were recruited and were between 38 and 70 years of age. The subjects consumed a low fat diet for a 2 week adjustment period and were then assigned to one of two treatment groups; low fat control diet with 20 g of corn bran supplement or the low fat control diet with 20 g wheat bran supplement. The subjects consumed their respective diets for 6 weeks and then consumed the other diet for an additional 6 weeks. Total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, very-low-density lipoprotein cholesterol and triglyceride concentrations were determined from fasting blood samples. Baseline blood samples were collected 7 days apart prior to the onset of the study. Blood was also collected at the start and end of the 2 week pre-period as well as the start and end of each 6 week treatment period. The low fat diet significantly lowered all parameters except the high density lipoprotein cholesterol. Corn fiber supplementation resulted in an additional lowering of serum total cholesterol, triglyceride, and VLDL-C concentrations. No adverse effects related to corn fiber consumption were reported during the study.

Kendall et al. (2008) studied the effect of a corn-based dietary fiber on postprandial glycemia. A rapid *in vitro* digestibility system and the blood glucose response were also evaluated. The twelve participants in this study (7 male and 5 female) were between 26 and 36 years of age with a body mass index of 24.9 ± 2.2 kg/m^2. Each subject consumed seven test beverages which contained the corn-based fiber ingredients (25 g total carbohydrate), along with two control meals, in random order on different days. The fiber ingredients tested included Pullulan, Promitor™ Soluble Corn Fiber 70, Promitor™ Resistant Starch 60, Promitor™ Resistant Starch 75, Soluble Fiber Dextrin, and a blend of Pullulan and Promitor™ Soluble Corn Fiber 70 (50:50). On the treatment day, the subjects were weighed, and fasting blood samples were collected. The subjects then consumed a test meal, and additional blood samples were collected at 15, 30, 45, 60, 90, and 120 minutes following the start of the meal. All corn dietary fibers and combinations resulted in glycemic and insulinemic responses which were significantly reduced compared to the glucose control. No adverse effects were reported in relation to the consumption of the corn fiber products.

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In another study, 125 subjects with mild to moderate hypercholesterolemia were used to evaluate the blood cholesterol-lowering effects of a dietary supplement of water-soluble and non-water soluble fibers (Knopp et al., 1999). In this study, mild to moderate hypercholesterolemia was defined as low density lipoprotein cholesterol of 3.37 to 4.92 mmol/L and triglycerides of ≤ 3.43 mmol/L. The water soluble fibers used in the study were guar gum and pectin while the non-water soluble fibers included soy fiber, pea fiber and corn bran. The subjects were between 18 and 70 years of age and were stabilized on a National Cholesterol Education Program Step 1 Diet for at least 9 weeks prior to randomization into the fiber supplement (n = 87) or placebo group(n = 82). The subjects in the fiber group received 20 g/day of the fiber supplement which consisted of 15 g/day of a mixture of guar gum and pectin and 5 g/day of a mixture of soy fiber, pea fiber and corn bran for the next 15 weeks while the other group consumed the placebo. Following the 15 weeks of placebo treatment, these subjects then received 20 g/day of fiber as well. The study continued for an additional 36 weeks. One hundred two subjects (52 fiber; 50 placebo) completed the 15-week comparative phase. Of these subjects 85 (45 fiber; 40 placebo) elected to continue in the 36-week noncomparative extension phase. Subjects returned every 3 weeks for the first 15 weeks for measurement of plasma total cholesterol, high-density lipoprotein and triglycerides and then every 6 weeks for the next 36 weeks. Prior to the start of treatment, at 6 and 15 weeks after treatment and then every 6 weeks for the next 36 weeks, plasma apolipoproteins A-1 and B concentrations, serum iron, ferritin and vitamins A and E concentrations were measured as well. During the initial 15 weeks of the study, 6% of the fiber group and 4% of the placebo group withdrew from the study due to treatment-related gastrointestinal side effects. From the subjects who continued after the first 15 weeks, 3% from the fiber group and 7% who were switched from placebo to fiber, withdrew from the study due to gastrointestinal side effects. During the first 15 weeks, 62% of the subjects in the fiber group and 49% of subjects in the placebo group reported side effects which were gastrointestinal in all but one subject per group. The majority of the side effects were mild and decreased with increasing duration of fiber supplement consumption. Increased diarrhea, rectal gas and loose stools were noted, as was a decreased incidence of constipation in the fiber group compared to placebo.

Mahalko et al. (1984) performed two studies in subjects with type II diabetes to investigate the effects of consuming various fibers on glucose and lipid metabolism. One study included 10 subjects who consumed 26 g of fiber source daily, while the second study included 8 subjects who consumed 52 g of fiber source per day. The subjects were given either low fiber bread as a control or bread containing one of three fiber sources which were incorporated into their usual diets. The fiber sources used included soy hull, corn bran or dehydrated powdered apple. The fiber sources were substituted for 25% of the white wheat flour in the bread. In the second study, half of the fiber was incorporated into the bread, and the rest was incorporated into other foods in their diet. Each subject consumed each fiber or control bread for 4 weeks; some subjects completed the control period at the end of the study again. At the beginning of the study and every two weeks thereafter, subjects kept a 3 day diet record and the following measurements were obtained; body weight, fasting plasma lipids, glycosylated hemoglobin, 24 hour urinary glucose measurements and a postprandial glucose tolerance test using a low fiber formula meal. In the study with 26 g of fiber, all subjects tolerated the fiber well, however, in the second study, the additional fiber was not well tolerated, especially the corn bran. Two subjects complained of an inability to consume the amount of bread and fiber provided while another had bowel impaction associated with the corn bran consumption. One additional subject complained of severe constipation which was associated with the consumption of the additional 26 g of corn bran fiber. In the second study, the addition of the corn bran had no effect on plasma or urinary glucose levels but did result in lower plasma low density lipoprotein cholesterol, triglyceride levels, and glycosylated hemoglobin levels compared to the white bread control, but when the values were compared to admission values, there were no differences in any of the measured variables.

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The effects of dietary fiber consumption on serum cholesterol were tested in healthy male subjects (Munoz et al., 1979). Ten healthy male volunteers between the ages of 19 and 54 years consumed a basal diet for 30 days, after which they ate 26 g of either soft white wheat bread, corn bran, soybean hull, textured vegetable protein, or hard red spring wheat bran for 28 to 30 days each. Each fiber was fed to four to six subjects. The diets were consumed in no particular order, and each subject consumed at least two different sources of dietary fiber. The fiber contents of the white wheat bread, corn bran, soybean hulls and hard red spring wheat bran were 44, 92, 87 and 51%, respectively. Twenty four hour urine and fecal collections were done daily. Each experimental period lasted 30 days and included 18 days for equilibration, followed by 12 days for balance collections. At the end of the 30 day period, subjects underwent a 12 hour fast, and fasting blood samples were then collected. Following blood collection, the subjects were given an oral carbohydrate load of 75 g in 325 mL of water to be consumed in 4 to 5 minutes. Venous blood samples were collected at 0, 30, 60, 120, and 180 minutes. Plasma triglycerides, total cholesterol, and high density lipoprotein cholesterol were all measured while low density lipoprotein cholesterol was calculated. Body composition was also determined during the study. Mean fecal weight increased with consumption of corn bran, soybean hulls, and hard red spring wheat bran while no effects were noted with the soft white wheat bread or textured vegetable protein. High density lipoprotein cholesterol and the ratio of high density lipoprotein cholesterol to total cholesterol did not change with any of the fiber sources while some triglyceride lowering effects were noted with all fiber sources. Total plasma cholesterol and low density lipoprotein cholesterol decreased with hard red spring wheat bran, and total serum cholesterol decreased with soybean hull fiber. The authors reported that the volunteers accepted the diet well and experienced no adverse effects.

Cherbut et al. (1997) investigated the physiological effects of corn and potato fibers on fasting and postprandial blood concentrations of carbohydrate and lipid metabolites, as well as on stool output and transit time in humans. The study comprised two one-month periods with an interval of 21 days. In this randomized, blind, crossover study, 18 healthy subjects (8 male, 10 female; 24-48 years of age) were divided in two groups and each group received 22 g of either corn or potato fiber twice daily which provided about 15 g fiber/day during one period and no fiber supplement replaced by sucrose (15 g/day) during the other period. Effects on fasting and postprandial blood concentrations of carbohydrate and lipid metabolites as well as on stool output and transit time were measured. Corn fiber resisted fermentation better than potato fiber and had lower digestibility. However, both fibers increased fecal output of dry matter, neutral sugars and water. There was an inverse relationship between stool weight and orofecal transit time, although only corn fiber significantly reduced transit time. The investigators suggested that these fibers would be suitable ingredients in a healthy diet. Apparently the fiber was well tolerated, as no adverse effects were reported.

E. Institute of Medicine Report

In 2005, the Institute of Medicine (IOM) Panel critically reviewed the safety related information on dietary fibers (IOM, 2005). The IOM Panel has not established a tolerable upper intake level (UL) for dietary or functional fiber. Regarding the adverse effects of dietary fibers, it was noted that the fibers--such as guar gum, inulin and oligofructose, fructooligosaccharides, polydextrose, resistant starch, and psyllium--can cause gastrointestinal distress which includes abdominal cramping, bloating, gas, and diarrhea (IOM, 2005; FDA, 2010b). In some individuals, an abrupt increase in the intake of dietary fiber may result in abdominal cramping, bloating or gas. Increasing the intake of fiber-rich foods gradually with an increase in fluid intake to about 2 liters/day can alleviate some of these symptoms. The addition of cereal fiber to meals has been suggested to decrease the gastrointestinal absorption of iron, zinc, calcium, and magnesium. It has been reported that phytate present in cereal fiber rather than the fiber itself may cause the decreased absorption. Generally, as part of a balanced diet, dietary fiber has not been found to adversely affect the calcium, magnesium, iron, or zinc status of healthy people at recommended intake levels. The safety of fiber is supported by several over-the-counter retail products that have been consumed successfully for their laxative effects, along with the various dietary uses of fiber in popular bakery goods, i.e., low-calorie-high-fiber breads (IOM, 2005; FDA, 2010b).

F. Dietary Fiber & Nutrients

It has been hypothesized that fiber intake may alter absorption of fat-soluble vitamins. The basis for such a hypothesis stems from the observation that certain dietary fibers delay absorption of triacylglycerol. Vitamin A absorption studies indicate that wheat bran consumption may either increase (Rattan et al., 1981) or decrease (Wahal et al., 1986) serum vitamin A levels. Limited information is available regarding the effects of consumption of specific fibers on absorption of other fat-soluble vitamins. The available studies on the effect of fiber on fat-soluble vitamin absorption are inconsistent. Compared to fat-soluble vitamins, the effect of fiber on absorption of water-soluble vitamins is even less understood. Available evidence suggests that wheat bran has no effect, while psyllium appeared to increase riboflavin absorption at pharmacological doses (Roe et al., 1988). Consumption of pectin fiber had no negative effect on the utilization of vitamin B_6 (Miller et al., 1980) or urinary ascorbic acid concentration (Keltz et al., 1978). Besides vitamins, the effects of various dietary fibers have also been investigated on mineral absorption. However, again, the results of these studies are inconsistent. There is lack of information to draw conclusions on the effects of particular fiber types (including corn fibers) or fiber mixtures on mineral absorption. The possibility that fiber consumption could impair mineral status has been raised; Gordon et al. (1995) has argued persuasively that evidence to support this contention is lacking. In summary, there is no compelling evidence to support the notion that consumption of corn fiber or soluble fibers impairs the absorption of vitamins or essential minerals in well nourished populations. Furthermore, there is a long history of consumption of fiber-rich foods without any major reports on vitamin-mineral mal-absorption from intake of fiber at currently recommended doses. Hence, it seems unlikely that the estimated increase in fiber intake from corn fiber would result in any significant adverse effects.

G. Dietary Fiber & Carcinogenesis

It is well recognized that a high intake of dietary fiber protects against cancer, especially colorectal cancer (Harris and Ferguson, 1999). Furthermore, the results of a large prospective epidemiological study did not reveal any apparent effect of dietary fiber intake on the development of colorectal cancer. It has been suggested that this may be related to the term "dietary fiber," which is rather general and represents a wide range of materials, some of which may be able to protect while some may enhance carcinogenesis. This possible view is consistent with data taken from animal carcinogenesis experiments. In four separate animal studies, effects of corn bran were investigated as summarized in Table 7. In three of the studies, corn bran administration increased the incidence of colon tumors. However, in one study, the incidence of colon tumors was reduced by corn bran administration. In the studies that showed an increased tumor incidence, the corn bran dose comprised quite a high proportion (15-20%) of the diet, while in the study where protection was noted the corn bran dose was relatively low (4.5%). Several factors such as type of fiber, composition of the fiber, levels of soluble and insoluble fiber, amount in the diet, etc., are known to affect tumor formation. The available animal studies indicate that, at very high levels, corn fiber increased the incidence of tumors while, at low levels, it reduced the incidence of tumor formation.

Table 7. Carcinogenicity-Related Studies of Corn Bran

Animal Species	Sex	Fiber Levels	Carcinogen	Effect	Reference
F344 rats	Male	20%	DMH	Increased incidence colon tumors	Barnes et al., 1983
F344 rats	Male	15%	DMAB	Increased incidence of colon cancer	Clapp et al., 1984
BALC/c mouse	Male	20%	DMH	Increased incidence colon tumors	Reddy et al., 1983
Wistar rats	Male	4.5%	DMH	Reduction in incidence of colon tumors	Freeman et al., 1984

DMH = 1,2-dimethylhydrazine; DMAB = 3,2'-dimethyl-4-aminobiphenyl.

H. Allergenicity Considerations with N-Corn Z Trim®

Corn is a cereal grain with proteins that are similar to those in other cereal grains, such as wheat. Individuals allergic to cereal grain products are not allergic to the fiber but to some of the specific proteins found in some cereals. In general, compared to the wheat, relatively few reports of allergic reactions to corn exist. The allergy related reports include anaphylaxis as a result of eating corn and corn-related foods, as well as reactions after exposure to cornstarch in surgical gloves. David (1984) described a report of anaphylaxis to a corn-induced reaction in a child on reintroduction of sweet corn after an elimination diet to treat eczema. The anaphylaxis reaction attributed to cornstarch in surgical glove powder has also been reported in a few case reports (Seggev et al., 1990; Assalve et al., 1988; Fisher, 1987). Pauls and Cross (1998) reported food-dependent exercise-induced anaphylaxis to corn in an adult. Although these studies suggest a corn-induced anaphylaxis reaction, only the study by Pauls and Cross (1998) was noted in a controlled setting. Tanaka et al. (2001) reported that a patient with classic anaphylaxis to corn was observed in a double-blind, placebo-controlled food challenge. In the study by Tanaka et al. (2001), a 44-year-old woman was evaluated. Skin prick testing revealed positive results for histamine (10 mm), cooked corn (10 mm), uncooked corn (35 mm), corn pollen (39 mm), peanut (28 mm), rice (20 mm), grass mix (20 mm), and dust mites (25 mm).The corn, placebo, and challenge vehicle extracts were tested. The patient experienced anaphylaxis after ingesting a total of 26 g of corn flour which is approximately equivalent to 6 corn chips.

The N-Corn Z Trim® manufacturing facility is allergen free. The Z Trim® Allergen Policy specifically refers to allergens as milk, eggs, peanuts, tree nuts, fish, shellfish, soy and wheat. It is the role of the Quality Assurance Director to maintain a supplier information and allergen declaration list from all vendors to ensure the maintenance of the allergen free status. ZTH acknowledges that N-Corn Z Trim® does not contain any of the eight foods---milk, egg, fish, crustacean shellfish, tree nuts, peanuts, soybeans, and wheat---considered to be major food allergens under the US Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA, 2004).

VI. DISCUSSION

A. GRAS Criteria

FDA defines "safe" or "safety" as it applies to food ingredients as:

> "...reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance."[5]

Amplification is provided in that the determination of safety is to include probable consumption of the substance in question, the cumulative effect of the substance and appropriate safety factors. It is FDA's operational definition of safety that serves as the framework against which this evaluation is provided.

Furthermore, in discussing GRAS criteria, FDA notes that:

> "...General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."
>
> "General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information."[6]

FDA discusses in more detail what is meant by the requirement of general knowledge and acceptance of pertinent information within the scientific community, i.e., the so-called "common knowledge element," in terms of the two following component elements:[7]

- Data and information relied upon to establish safety must be generally available, and this is most commonly established by utilizing published, peer-reviewed scientific journals; and

- There must be a basis to conclude that there is consensus (but not unanimity) among qualified scientists about the safety of the substance for its intended use, and this is established by relying upon secondary scientific literature such as published review articles, textbooks, or compendia, or by obtaining opinions of expert panels or opinions from authoritative bodies, such as JECFA and the National Academy of Sciences.

The apparent imprecision of the terms "appreciable," "at the time," and "reasonable certainty" demonstrates that the FDA recognizes the impossibility of providing absolute safety in this or any other area (Lu, 1988; Renwick, 1990, Rulis and Levitt, 2009).

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[5] See 21 CFR 170.3(i).
[6] See 21 CFR 170.30(a).
[7] See Footnote 1.

As noted below, this safety assessment to ascertain GRAS status for corn derived dietary fiber for the defined food uses meets FDA criteria for reasonable certainty of no harm by considering both the technical and common knowledge elements.

B. Safety of N-Corn Z Trim®

The Panel has reviewed the manufacturing process, specifications and composition of N-Corn Z Trim® as well as the information on the history of use of corn and corn products in food. In addition, the studies addressing the safety of corn bran, corn fiber and Corn Z Trim® were evaluated by the Panel. The Panel recognizes the long history of safe use of corn fiber in the US and around the world. N-Corn Z Trim® is manufactured in a HACCP-designed facility in compliance with Good Manufacturing Practices and Food Safety Systems, and all ingredients used in the production of N-Corn Z Trim® have GRAS status or are regulated as food additives; furthermore, the final product is tested for adherence to predetermined product specifications and for specific contaminants. ZTH has established adequate food grade specifications for N-Corn Z-Trim®.

The Panel agrees that N-Corn Z Trim® has a high presumption of safety because it is a mildly processed fraction of corn. Given the long history of safe dietary uses of corn, including its fiber, no safety concerns were raised for N-Corn Z Trim® even though there are no well-designed animal studies and only a few human studies which demonstrate the absence of adverse effects from corn or corn fiber consumption. In particular, the available clinical studies of corn bran (fiber) support the safety of this food ingredient.

The studies indicating variable effects of corn fiber on experimentally induced tumors were reviewed, and the Panel agrees that the results do not raise any safety concern for corn products consumed under normal dietary situations. The Panel also notes that FDA has recognized the GRAS status of dietary fiber products extracted from other common food sources such as barley, carrots, oats, potatoes, and oranges. In each of these assessments, little specific safety data on the specific ingredient were available, and the respective safety assessments relied extensively on the fact that the ingredients were extracted from commonly consumed foods where the processing steps were not expected to cause any adverse changes in the composition of the extracted ingredients. In the case of N-Corn Z Trim,® the chemicals used in the process are safe for use and are well known for their uses in other carbohydrate based products----specifically modified food starches---they are not expected to cause any chemical changes in carbohydrate molecules that would trigger a safety concern.

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As presented, the levels of N-Corn Z Trim® that will be used in food products are self-limiting based on the fact that over use in foods will result in products that have unacceptable properties to the consumer, e.g., food texture. The maximum estimated daily intake of N-Corn Z Trim® is determined as 27.0 g/person/day, which corresponds to a fiber intake estimate of 24.8 g/person/day. With a recommended daily intake of between 25and 38 g of dietary fiber per day for individuals over 3 years of age (IOM, 2005) and between 22 and 34 g of dietary fiber per day for adults (USHHS/USDA, 2010), the consumption estimate of N-Corn Z Trim® from its intended uses does not present a safety concern, and such intake of dietary fiber may bring fiber consumption closer to optimum levels as recommended by the authoritative bodies noted in Section V.A. In particular, the IOM-recommended intake levels for total dietary fibers range from 25 to 38 g/day.

However, the current dietary fiber intake in the US of 12 to18 g/person is significantly lower than the recommended levels. The daily reference value for dietary fiber for a 2000 calorie diet is 25 g (21 CFR 101.9(d)). Compared to the recommended daily intake of dietary fiber, the intake of corn fiber of 24 g person/day from the intended uses of N-Corn Z Trim® is similar to the recommended daily intake.

The totality of available evidence from dietary consumption of corn, including corn and its fiber, for centuries, current intake of dietary fiber, and *in vitro,* animal testing, and human studies suggest that consumption of corn fiber from the intended uses of N-Corn Z Trim® at use levels ranging from 0.1%to 3% in baked goods, bread and coatings, dairy products, egg products, meat and poultry products, dressings, dips, soups, gravies, sauces, snacks, fillings, toppings and icings is safe. On the basis of scientific procedures and as corroborated by historical consumption of corn and corn fiber from natural dietary sources, the Expert Panel considers the consumption of N-Corn Z Trim® as an added food ingredient to be safe at daily consumption levels up to 27.0g/person which corresponds to daily per capita consumption of up to 24.8g of corn fiber.

C. Common Knowledge Elements for GRAS Determinations

The first common knowledge element for a GRAS determination requires that data and information relied upon to establish safety must be generally available; this is most commonly established by utilizing published, peer-reviewed scientific journals for the safety assessment. The common use of corn in food on a global basis and the associated absence of harm from different sources of dietary fiber is based on published information (IOM, 2005; Rose et al., 2010). In addition, the clinical studies which support the safety assessment have been published in the scientific literature (Shane and Walker, 1995; Cherbut et al., 1997; Knopp et al., 1999).

The second common knowledge element for a GRAS determination is that there must be consensus among qualified scientists about the safety of the substance with its intended use.

Many competent researchers responsible for the data referred to in this safety evaluation that have expertise in the fields of agriculture, nutrition, toxicology and medicine view corn as a viable source of food and a viable source of certain nutrients with an unequivocal and sustained record of safety.

The Panel concludes that general consensus exists regarding the safety of the intended human food uses of N-Corn Z Trim® based on the following findings:

- The process for N-Corn Z Trim® was developed by USDA scientists who recognized the value of dietary fiber and the safe source of corn.
- No adverse effects associated with the consumption of corn or corn fiber were identified in the scientific literature that dates into the 1800s.

VII. CONCLUSIONS[8]

The Panel offers the following conclusion:

> **Corn fiber, as described herein as N-Corn Z Trim®, that is produced in accordance with FDA Good Manufacturing Practices requirements which also meets the purity specifications as set forth in Table 2 within Section III.C, is generally recognized as safe when consumed at daily levels up to 27.0 grams (corresponding to 24.8 grams of fiber) per person in the food categories and at the designated food use levels specified in Table 5.**

This declaration is made in accordance with FDA's standard for food ingredient safety, i.e., reasonable certainty of no harm under the intended conditions of use.

(b) (6)

Richard C. Kraska, Ph.D., DABT

(b) (6)

Robert S. McQuate, Ph.D.

(b) (6)

Madhusudan G. Soni, Ph.D., FACN, FATS

March 5, 2012

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8 The detailed educational and professional credentials for two the individuals serving on the Expert Panel can be found on the GRAS Associates website at www.gras-associates.com. Drs. Kraska and McQuate worked on GRAS and food additive safety issues within FDA's GRAS Review Branch earlier in their careers and subsequently continued working within this area in the private sector. Dr. Soni's curriculum vitae can be accessed at http://www.soniassociates.net All three panelists have extensive technical backgrounds in the evaluation of food ingredient safety. Each individual has previously served on multiple GRAS Expert Panels. Dr. Kraska served as Chair of the Panel.

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APPENDIX A -- N-CORN Z TRIM® TESTING RESULTS

Appendix A-1

N·PAL
N·P ANALYTICAL LABORATORIES

A Nestlé Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

ANALYSIS REPORT

To: JONATHAN WALL (ES)
Z TRIM HOLDINGS
1010 CAMPUS DRIVE
MUNDELEIN IL 60060

CC:

Page 1 of 3

Sample No.: L1122108-1 **Receipt Date:** 09/27/2011

Report Date: 10/10/2011

(b) [redacted]

Test Code	Assay / Analyte	Result	Units
LIGF	**Lignin, permanganate**		
	Lignin	< 0.2	%
NDF	**Fiber, Neutral detergent**		
	Neutral Detergent Fiber	86.4	%
ADF	**Fiber, acid detergent**		
	Acid Detergent Fiber	49.4	%
FIBR	**Fiber, crude**		
	Fiber - Crude	47.4	%
PDFF	**Dietary Fiber, AOAC sol. & insol.**		
	Insoluble Dietary Fiber	87.9	%
	Soluble Fiber	2.99	%
	Total Dietary Fiber	90.9	%
ASHF	**Ash, 600C**		
	Ash	1.21	%
AS	**Arsenic**		
	Arsenic	< 0.20	ppm
CDF	**Cadmium**		
	Cadmium	< 0.0500	ppm
PB	**Lead**		
	Lead	< 0.0500	ppm
HG	**Mercury, by Thermal Decomposition**		
	Mercury	< 0.025	ppm

Person responsible for report content: Lynn Loudermilk, Director.

The test code located next to each assay is a method reference code. Results are for samples submitted only. This report shall not be reproduced, except in its entirety, without the written permission of NP Analytical Laboratories.

For additional information, contact Customer Services at 800-423-6832 or 314-982-1310.

 CH2011101019360189

The symbol "<" or the words "less than" signifies that no analyte was measured at or above the stated lower limit of quantitation of the procedure under the conditions employed. The use of the symbol "<" or the words "less than" does not imply that traces of the analyte were present. The symbol ">" or the term "greater than" signifies that the analyte was determined to be present in an amount greater than the stated level. Samples submitted to NP Analytical Laboratories for testing are retained for a minimum of thirty (30) days after the analysis report is issued when sample stability permits. Requests for extended storage must be made to NP Analytical Laboratories prior to or at the time of sample submission.

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N•PAL
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A Nestle' Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

Sample No.: L1122108-1 **Received:** 09/27/2011 **Page 2 of 3**

Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
K	**Potassium**			
		Potassium	163	ppm
ORGP	**Organophosphate pesticides**			
		Diazinon	< 0.0200	ppm
		Disulfoton	< 0.0200	ppm
		Ethion	< 0.0200	ppm
		Malathion	< 0.0200	ppm
		Methyl Parathion	< 0.0200	ppm
		Parathion	< 0.0200	ppm
		Thimet	< 0.0200	ppm
		Thiodan	< 0.0200	ppm
		Trithion	< 0.0200	ppm
RSPB	**Organochlorine pest.&PCB's**			
		Heptachlor Epoxide	< 0.0200	ppm
		Heptachlor	< 0.0200	ppm
		DDE	< 0.0200	ppm
		Lindane	< 0.0200	ppm
		Endrin	< 0.0200	ppm
		Mirex	< 0.0200	ppm
		Alpha-BHC	< 0.0200	ppm
		Delta-BHC	< 0.0200	ppm
		Aldrin	< 0.0200	ppm
		Dieldrin	< 0.0200	ppm
		DDT	< 0.0200	ppm
		Chlordane	< 0.0200	ppm
		Methoxychlor	< 0.0200	ppm
		Beta-BHC	< 0.0200	ppm
		HCB	< 0.0200	ppm
		PCB	< 0.150	ppm
AFTX	**Aflatoxin screen, ELISA**			
		Aflatoxins	< 10	ppb
DONE	**Deoxynivalenol (ELISA)**			

Person responsible for report content: Lynn Loudermilk, Director.

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 CH2011101019360190

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A Nestle' Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

Sample No.: L1122108-1 **Received:** 09/27/2011 **Page 3 of 3**

Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
	Vomitoxin	< 1.00	ppm

Person responsible for report content: Lynn Loudermilk, Director.

000042

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CH2011101019360191

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N-PAL
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A Nestle' Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

ANALYSIS REPORT

To: JONATHAN WALL (ES)
Z TRIM HOLDINGS
1010 CAMPUS DRIVE
MUNDELEIN IL 60060

CC:

Page 1 of 3

Sample No.: L1122108-2 **Receipt Date:** 09/27/2011

Report Date: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
LIGF	**Lignin, permanganate**		
	Lignin	< 0.2	%
NDF	**Fiber, Neutral detergent**		
	Neutral Detergent Fiber	71.6	%
ADF	**Fiber, acid detergent**		
	Acid Detergent Fiber	49.1	%
FIBR	**Fiber, crude**		
	Fiber - Crude	46.5	%
PDFF	**Dietary Fiber, AOAC sol. & insol.**		
	Insoluble Dietary Fiber	84.4	%
	Soluble Fiber	3.25	%
	Total Dietary Fiber	87.7	%
ASHF	**Ash, 600C**		
	Ash	2.08	%
AS	**Arsenic**		
	Arsenic	< 0.20	ppm
CDF	**Cadmium**		
	Cadmium	< 0.0500	ppm
PB	**Lead**		
	Lead	< 0.0500	ppm
HG	**Mercury, by Thermal Decomposition**		
	Mercury	< 0.025	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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Sample No.: L1122108-2 **Received:** 09/27/2011 **Reported:** 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
K	**Potassium**			
		Potassium	216	ppm
ORGP	**Organophosphate pesticides**			
		Diazinon	< 0.0200	ppm
		Disulfoton	< 0.0200	ppm
		Ethion	< 0.0200	ppm
		Malathion	< 0.0200	ppm
		Methyl Parathion	< 0.0200	ppm
		Parathion	< 0.0200	ppm
		Thimet	< 0.0200	ppm
		Thiodan	< 0.0200	ppm
		Trithion	< 0.0200	ppm
RSPB	**Organochlorine pest.&PCB's**			
		Heptachlor Epoxide	< 0.0200	ppm
		Heptachlor	< 0.0200	ppm
		DDE	< 0.0200	ppm
		Lindane	< 0.0200	ppm
		Endrin	< 0.0200	ppm
		Mirex	< 0.0200	ppm
		Alpha-BHC	< 0.0200	ppm
		Delta-BHC	< 0.0200	ppm
		Aldrin	< 0.0200	ppm
		Dieldrin	< 0.0200	ppm
		DDT	< 0.0200	ppm
		Chlordane	< 0.0200	ppm
		Methoxychlor	< 0.0200	ppm
		Beta-BHC	< 0.0200	ppm
		HCB	< 0.0200	ppm
		PCB	< 0.150	ppm
AFTX	**Aflatoxin screen, ELISA**			
		Aflatoxins	< 10	ppb
DONE	**Deoxynivalenol (ELISA)**			

Person responsible for report content: Lynn Loudermilk, Director.

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 CH2011101019360193

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Sample No.: L1122108-2 **Received:** 09/27/2011 **Reported:** 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
	Vomitoxin	< 1.00	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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 CH2011101019360194

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N·PAL N·P ANALYTICAL LABORATORIES

A Nestlé Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

ANALYSIS REPORT

To: JONATHAN WALL (ES)
Z TRIM HOLDINGS
1010 CAMPUS DRIVE
MUNDELEIN IL 60060

CC:

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Sample No.: L1122108-3 **Receipt Date:** 09/27/2011
Report Date: 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
LIGF	**Lignin, permanganate**			
		Lignin	< 0.2	%
NDF	**Fiber, Neutral detergent**			
		Neutral Detergent Fiber	84.9	%
ADF	**Fiber, acid detergent**			
		Acid Detergent Fiber	51.3	%
FIBR	**Fiber, crude**			
		Fiber - Crude	48.7	%
PDFF	**Dietary Fiber, AOAC sol. & insol.**			
		Insoluble Dietary Fiber	85.2	%
		Soluble Fiber	2.84	%
		Total Dietary Fiber	88.0	%
ASHF	**Ash, 600C**			
		Ash	2.55	%
AS	**Arsenic**			
		Arsenic	< 0.20	ppm
CDF	**Cadmium**			
		Cadmium	< 0.0500	ppm
PB	**Lead**			
		Lead	< 0.0500	ppm
HG	**Mercury, by Thermal Decomposition**			
		Mercury	< 0.025	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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 CH2011101019360195

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Sample No.: L1122108-3 **Received:** 09/27/2011 Page 2 of 3

Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
K	**Potassium**			
		Potassium	176	ppm
ORGP	**Organophosphate pesticides**			
		Diazinon	< 0.0200	ppm
		Disulfoton	< 0.0200	ppm
		Ethion	< 0.0200	ppm
		Malathion	< 0.0200	ppm
		Methyl Parathion	< 0.0200	ppm
		Parathion	< 0.0200	ppm
		Thimet	< 0.0200	ppm
		Thiodan	< 0.0200	ppm
		Trithion	< 0.0200	ppm
RSPB	**Organochlorine pest.&PCB's**			
		Heptachlor Epoxide	< 0.0200	ppm
		Heptachlor	< 0.0200	ppm
		DDE	< 0.0200	ppm
		Lindane	< 0.0200	ppm
		Endrin	< 0.0200	ppm
		Mirex	< 0.0200	ppm
		Alpha-BHC	< 0.0200	ppm
		Delta-BHC	< 0.0200	ppm
		Aldrin	< 0.0200	ppm
		Dieldrin	< 0.0200	ppm
		DDT	< 0.0200	ppm
		Chlordane	< 0.0200	ppm
		Methoxychlor	< 0.0200	ppm
		Beta-BHC	< 0.0200	ppm
		HCB	< 0.0200	ppm
		PCB	< 0.150	ppm
AFTX	**Aflatoxin screen, ELISA**			
		Aflatoxins	< 10	ppb
DONE	**Deoxynivalenol (ELISA)**			

Person responsible for report content: Lynn Loudermilk, Director.

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Sample No.: L1122108-3 **Received:** 09/27/2011 **Page 3 of 3**

Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
	Vomitoxin	< 1.00	ppm

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A Nestlé Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

ANALYSIS REPORT

To: JONATHAN WALL (ES)
Z TRIM HOLDINGS
1010 CAMPUS DRIVE
MUNDELEIN IL 60060

CC:

Page 1 of 3

Sample No.: L1122108-4 **Receipt Date:** 09/27/2011
Report Date: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
LIGF	**Lignin, permanganate**		
	Lignin	< 0.2	%
NDF	**Fiber, Neutral detergent**		
	Neutral Detergent Fiber	85.8	%
ADF	**Fiber, acid detergent**		
	Acid Detergent Fiber	51.1	%
FIBR	**Fiber, crude**		
	Fiber - Crude	47.6	%
PDFF	**Dietary Fiber, AOAC sol. & insol.**		
	Insoluble Dietary Fiber	85.9	%
	Soluble Fiber	3.71	%
	Total Dietary Fiber	89.6	%
ASHF	**Ash, 600C**		
	Ash	1.60	%
AS	**Arsenic**		
	Arsenic	< 0.20	ppm
CDF	**Cadmium**		
	Cadmium	< 0.0500	ppm
PB	**Lead**		
	Lead	< 0.0500	ppm
HG	**Mercury, by Thermal Decomposition**		
	Mercury	< 0.025	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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Checkerboard Square • St. Louis, MO 63164

Sample No.: L1122108-4 **Received:** 09/27/2011 Page 2 of 3
Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
K	**Potassium**			
		Potassium	157	ppm
ORGP	**Organophosphate pesticides**			
		Diazinon	< 0.0200	ppm
		Disulfoton	< 0.0200	ppm
		Ethion	< 0.0200	ppm
		Malathion	< 0.0200	ppm
		Methyl Parathion	< 0.0200	ppm
		Parathion	< 0.0200	ppm
		Thimet	< 0.0200	ppm
		Thiodan	< 0.0200	ppm
		Trithion	< 0.0200	ppm
RSPB	**Organochlorine pest.&PCB's**			
		Heptachlor Epoxide	< 0.0200	ppm
		Heptachlor	< 0.0200	ppm
		DDE	< 0.0200	ppm
		Lindane	< 0.0200	ppm
		Endrin	< 0.0200	ppm
		Mirex	< 0.0200	ppm
		Alpha-BHC	< 0.0200	ppm
		Delta-BHC	< 0.0200	ppm
		Aldrin	< 0.0200	ppm
		Dieldrin	< 0.0200	ppm
		DDT	< 0.0200	ppm
		Chlordane	< 0.0200	ppm
		Methoxychlor	< 0.0200	ppm
		Beta-BHC	< 0.0200	ppm
		HCB	< 0.0200	ppm
		PCB	< 0.150	ppm
AFTX	**Aflatoxin screen, ELISA**			
		Aflatoxins	< 10	ppb
DONE	**Deoxynivalenol (ELISA)**			

Person responsible for report content: Lynn Loudermilk, Director.

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Sample No.: L1122108-4 **Received:** 09/27/2011 **Page 3 of 3**

Reported: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
	Vomitoxin	< 1.00	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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A Nestlé Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

ANALYSIS REPORT

To: JONATHAN WALL (ES)
Z TRIM HOLDINGS
1010 CAMPUS DRIVE
MUNDELEIN IL 60060

CC:

Page 1 of 3

Sample No.: L1122108-5 **Receipt Date:** 09/27/2011
Report Date: 10/10/2011

(b) (4)

Test Code	Assay / Analyte	Result	Units
LIGF	**Lignin, permanganate**		
	Lignin	< 0.2	%
NDF	**Fiber, Neutral detergent**		
	Neutral Detergent Fiber	85.9	%
ADF	**Fiber, acid detergent**		
	Acid Detergent Fiber	49.8	%
FIBR	**Fiber, crude**		
	Fiber - Crude	47.0	%
PDFF	**Dietary Fiber, AOAC sol. & insol.**		
	Insoluble Dietary Fiber	87.2	%
	Soluble Fiber	4.75	%
	Total Dietary Fiber	92.0	%
ASHF	**Ash, 600C**		
	Ash	1.08	%
AS	**Arsenic**		
	Arsenic	< 0.20	ppm
CDF	**Cadmium**		
	Cadmium	< 0.0500	ppm
PB	**Lead**		
	Lead	< 0.0500	ppm
HG	**Mercury, by Thermal Decomposition**		
	Mercury	< 0.025	ppm

Person responsible for report content: Lynn Loudermilk, Director.

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Sample No.: L1122108-5 **Received:** 09/27/2011 **Reported:** 10/10/2011

(b) (4)

Test Code	Assay / Analyte		Result	Units
K	**Potassium**			
		Potassium	295	ppm
ORGP	**Organophosphate pesticides**			
		Diazinon	< 0.0200	ppm
		Disulfoton	< 0.0200	ppm
		Ethion	< 0.0200	ppm
		Malathion	< 0.0200	ppm
		Methyl Parathion	< 0.0200	ppm
		Parathion	< 0.0200	ppm
		Thimet	< 0.0200	ppm
		Thiodan	< 0.0200	ppm
		Trithion	< 0.0200	ppm
RSPB	**Organochlorine pest.&PCB's**			
		Heptachlor Epoxide	< 0.0200	ppm
		Heptachlor	< 0.0200	ppm
		DDE	< 0.0200	ppm
		Lindane	< 0.0200	ppm
		Endrin	< 0.0200	ppm
		Mirex	< 0.0200	ppm
		Alpha-BHC	< 0.0200	ppm
		Delta-BHC	< 0.0200	ppm
		Aldrin	< 0.0200	ppm
		Dieldrin	< 0.0200	ppm
		DDT	< 0.0200	ppm
		Chlordane	< 0.0200	ppm
		Methoxychlor	< 0.0200	ppm
		Beta-BHC	< 0.0200	ppm
		HCB	< 0.0200	ppm
		PCB	< 0.150	ppm
AFTX	**Aflatoxin screen, ELISA**			
		Aflatoxins	< 10	ppb
DONE	**Deoxynivalenol (ELISA)**			

Person responsible for report content: Lynn Loudermilk, Director.

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N·P ANALYTICAL LABORATORIES

A Nestle Purina PetCare Company
Checkerboard Square • St. Louis, MO 63164

Sample No.: L1122108-5 **Received:** 09/27/2011 **Page 3 of 3**

Reported: 10/10/2011

(b) (4) B

Test Code	Assay / Analyte	Result	Units
	Vomitoxin	< 1.00	ppm

Person responsible for report content: Lynn Loudermilk, Director.

The test code located next to each assay is a method reference code. Results are for samples submitted only. This report shall not be reproduced, except in its entirety, without the written permission of NP Analytical Laboratories.

For additional information, contact Customer Services at 800-423-6832 or 314-982-1310.

The information contained in this document is being transmitted in confidence. If you have received this document in error, please notify NPAL and destroy the document. CH2011101019360203

The symbol "<" or the words "less than" signifies that no analyte was measured at or above the stated lower limit of quantitation of the procedure under the conditions employed. The use of the symbol "<" or the words "less than" does not imply that traces of the analyte were present. The symbol ">" or the term "greater than" signifies that the analyte was determined to be present in an amount greater than the stated level. Samples submitted to NP Analytical Laboratories for testing are retained for a minimum of thirty (30) days after the analysis report is issued when sample stability permits. Requests for extended storage must be made to NP Analytical Laboratories prior to or at the time of sample submission.

000054

Appendix A-2

SILLIKER
a Mérieux NutriSciences Company
SILLIKER, Inc.
Illinois Laboratory
1304 Halsted Street, Chicago Heights, IL 60411
Tel. 877/ 777 6375 Fax. 708/ 756 0049

CERTIFICATE OF ANALYSIS

COA No:	CHG-35108106-0
Supersedes:	CHG-35089017-0
COA Date	2/22/12
Page 1 of 3	

COPY TO:
Mr. Jonathan Wall
Z Trim Holdings Inc
1011 Campus Dr
Mundelein, IL 60060

ORIGINAL TO:
Ms. Lynda Carroll
Director of QA and Technical Services
Z Trim Holdings Inc.
1011 Campus Dr.
Mundelein, IL 60060

Received From:	Mundelein, IL
Received Date:	9/26/11
P.O.# / ID:	JW 9.24.2010
Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Corn Fiber — **Laboratory ID:** 328977853
Desc. 2: Lot#/Sample Code: (b) (4) — **Condition Rec'd:** NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Calcium	309	mg/100g	AOAC 984.27	9/29/11	
Ewers Starch	5.9	% (w/w)	EC L123/72	10/5/11	MIN
Fat - Mojo, Acid Hydrolysis	1.09	% (w/w)	AOAC 933.05	9/30/11	
Iron	1.16	mg/100g	AOAC 984.27	9/29/11	
Moisture - Vacuum Oven	6.69	% (w/w)	AOAC 926.08	9/29/11	
Protein - Kjeldahl			AOAC 991.20.I	9/30/11	
Protein Factor	6.25	-			
As Received	0.18	% (w/w)			
Sodium	193	mg/100g	AOAC 984.27	9/29/11	

Desc. 1: Corn Fiber — **Laboratory ID:** 328977882
Desc. 2: Lot#/Sample Code: (b) (4) — **Condition Rec'd:** NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Calcium	209	mg/100g	AOAC 984.27	9/29/11	
Ewers Starch	6.5	% (w/w)	EC L123/72	10/5/11	MIN
Fat - Mojo, Acid Hydrolysis	0.90	% (w/w)	AOAC 933.05	9/30/11	
Iron	1.18	mg/100g	AOAC 984.27	9/29/11	
Moisture - Vacuum Oven	6.41	% (w/w)	AOAC 926.08	9/29/11	
Protein - Kjeldahl			AOAC 991.20.I	9/30/11	
Protein Factor	6.25	-			
As Received	<0.12	% (w/w)			
Sodium	682	mg/100g	AOAC 984.27	9/29/11	

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Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Corn Fiber — **Laboratory ID:** 328977892
Desc. 2: Lot#/Sample Code:(b) (4) 3 — **Condition Rec'd:** NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Calcium	329	mg/100g	AOAC 984.27	9/29/11	
Ewers Starch	6.3	% (w/w)	EC L123/72	10/5/11	MIN
Fat - Mojo, Acid Hydrolysis	1.21	% (w/w)	AOAC 933.05	9/30/11	
Iron	0.94	mg/100g	AOAC 984.27	9/29/11	
Moisture - Vacuum Oven	6.68	% (w/w)	AOAC 926.08	9/29/11	
Protein - Kjeldahl			AOAC 991.20.I	9/30/11	
Protein Factor	6.25	-			
As Received	0.14	% (w/w)			
Sodium	367	mg/100g	AOAC 984.27	9/29/11	

Desc. 1: Corn Fiber — **Laboratory ID:** 328977909
Desc. 2: Lot#/Sample Code: NCZT 918488 — **Condition Rec'd:** NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Calcium	181	mg/100g	AOAC 984.27	9/29/11	
Ewers Starch	6.9	% (w/w)	EC L123/72	10/5/11	MIN
Fat - Mojo, Acid Hydrolysis	0.98	% (w/w)	AOAC 933.05	9/30/11	
Iron	1.22	mg/100g	AOAC 984.27	9/29/11	
Moisture - Vacuum Oven	6.41	% (w/w)	AOAC 926.08	9/29/11	
Protein - Kjeldahl			AOAC 991.20.I	9/30/11	
Protein Factor	6.25	-			
As Received	0.18	% (w/w)			
Sodium	311	mg/100g	AOAC 984.27	9/29/11	

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Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Corn Fiber
Desc. 2: Lot#/Sample Code: (b) (4)

Laboratory ID: 328977922
Condition Rec'd: NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Calcium	160	mg/100g	AOAC 984.27	9/29/11	
Ewers Starch	4.9	% (w/w)	EC L123/72	10/5/11	MIN
Fat - Mojo, Acid Hydrolysis	1.09	% (w/w)	AOAC 933.05	9/30/11	
Iron	1.10	mg/100g	AOAC 984.27	9/29/11	
Moisture - Vacuum Oven	6.41	% (w/w)	AOAC 926.08	9/29/11	
Protein - Kjeldahl			AOAC 991.20.I	9/30/11	
Protein Factor	6.25	-			
As Received	<0.12	% (w/w)			
Sodium	1110	mg/100g	AOAC 984.27	9/29/11	

(b) (6)

Randy Fleener / Laboratory Director

Noted Test Locations: MIN-Silliker, Inc. Minnesota Laboratory, 11585 K-Tel Drive, Minnetonka, MN 55343

Appendix A-3

Summary of Testing Five Production Lots Versus Product Specifications

	Specification	(b) (4)	(b) (4)	(b) (4)	(b) (4) (b) (4)	(b) (4) (b) (4)	Method	Data Source
Internal COA								
Appearance	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Visual inspection	Appendix A-4
Odor	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless	Organoleptic	Appendix A-4
Taste	Tasteless	Tasteless	Tasteless	Tasteless	Tasteless	Tasteless	Organoleptic	Appendix A-4
Moisture	< 8.0%	6.55	6.75	6.05	6.95	7.39	Ohaus M45	Appendix A-4
Color								
L	*L>82.00*	85.29	86.43	87.68	88.01	87.32	Hunter colorflex	Appendix A-4
a	*- 0.80 – 3.00*	1.41	1.99	1.51	1.76	1.12	Hunter colorflex	Appendix A-4
b	*8.00-18.00*	14.17	14.24	12.35	11.80	14.22	Hunter colorflex	Appendix A-4
Ash	< 3.5%	2.26	0.7	1.4	0.7	0.57	CRA A-5	Appendix A-2
Total Dietary Fiber	87-92%	90.9	92.0	89.6	88.0	87.7	AOAC 985.29	Appendix A-1
Sodium	1500 mg/100g	1110	193	682	367	311	AOAC 984.27	Appendix A-2
Arsenic	< 0.2 ppm	<0.20	<0.20	<0.20	<0.20	<0.20	Atomic Absorption	Appendix A-1

Cadmium	< 0.2 ppm	<0.0500	<0.0500	<0.0500	<0.0500	<0.0500	Atomic Absorption	Appendix A-1
Lead	< 0.2 ppm	<0.0500	<0.0500	<0.0500	<0.0500	<0.0500	Atomic Absorption	Appendix A-1
Mercury	< 0.2 ppm	<0.025	<0.025	<0.025	<0.025	<0.025	Atomic Absorption	Appendix A-1
APC	< 10 cfu/g	<10	<10	190	<10	<10	AOAC 966.23	Appendix A-4
E.coli	< 10 cfu/g	<10	<10	<10	<10	<10	AOAC 991.14	Appendix A-4
Coliform	< 10 cfu/g	<10	<10	<10	<10	<10	AOAC 991.14	Appendix A-4
Yeast	< 10 cfu/g	<10	<10	<10	<10	<10	FDA BAM 8ed ch18	Appendix A-4
Mold	< 10 cfu/g	<10	<10	<10	<10	<10	FDA BAM 8ed ch18	Appendix A-4
Salmonella /25g	Negative /25g	Negative	Negative	Negative	Negative	Negative	FDA BAM 8ed ch.5	Appendix A-4

Appendix A-4

Z-TRIM INGREDIENTS

1011 Campus Drive,
Mundein, IL 60060,
(847) 549-6002,
www.ztrim.com

CERTIFICATE OF ANALYSIS

Country of Manufacture:	USA
Lot No:	(b) (4)
Z-Trim Powder	Multi-functional corn ingredient
Ingredient Statement:	Corn Fiber, Less than 0.50% of Sunflower Lecithin & DL-a-Tocopheryl acetate (Vitamin E).

Organoleptic Data: Off-white powder with some brown and black specs, odorless, tasteless.

Physical Data:

Color L Value	L = 87.68	a = 1.51	b = 12.35
Viscosity	24131 cps	Temp at 28.0 °C, 4% solids Shear-thinning thixotropic gel	
Moisture	6.05 %		

Microbiological Data:

APC, (FDA BAM)	190 cfu/g	
Yeast (FDA BAM)	<10 cfu/g	
Mold, (FDA BAM)	<10 cfu/g	
E. Coli (Petrifilm)	<10 cfu/g	
Coliform (Petrifilm)	<10 cfu/g	
Salmonella (FDA BAM)	Negative	/ 25g

Shelf Life: Two years if stored under cool dry conditions in a sealed container

Date of Manufacturing:	August 17, 2011
Expiration Date:	August 16, 2013
Date of Certification:	September 1, 2011

(b) (6)

Quality Assurance Manager
Jonathan Wall

Coa Corn Rev05.24.2010

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Z-TRIM
INGREDIENTS

1011 Campus Drive,
Mundein, IL 60060,
(847) 549-6002,
www.ztrim.com

CERTIFICATE OF ANALYSIS

Country of Manufacture:	**USA**
Lot No:	(b) (4) [redacted]3
Z-Trim Powder	Multi-functional corn ingredient
Ingredient Statement:	Corn Fiber, Less than 0.50% of Sunflower Lecithin & DL-a-Tocopheryl acetate (Vitamin E).

Organoleptic Data:	White to off-white powder, odorless, tasteless.		
Physical Data:			
Color L Value	L = 88.01	a = 1.76	b = 11.80
Viscosity	20257 cps	Temp at 29.2 °C, 4% solids Shear-thinning thixotropic gel	
Moisture	6.95 %		
Microbiological Data:			
APC, (FDA BAM)	<10 cfu/g		
Yeast (FDA BAM)	<10 cfu/g		
Mold, (FDA BAM)	<10 cfu/g		
E. Coli (Petrifilm)	<10 cfu/g		
Coliform (Petrifilm)	<10 cfu/g		
Salmonella (FDA BAM)	Negative	/ 25g	

Shelf Life: Two years if stored under cool dry conditions in a sealed container

Date of Manufacturing:	August 16, 2011
Expiration Date:	August 15, 2013
Date of Certification:	August 29, 2011

(b) (6) [redacted]

Quality Assurance Manager
Jonathan Wall

Coa Corn Rev05.24.2010

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Z-TRIM
INGREDIENTS

1011 Campus Drive,
Mundein, IL 60060,
(847) 549-6002,
www.ztrim.com

CERTIFICATE OF ANALYSIS

Country of Manufacture:	USA
Lot No:	(b) (4)
Z-Trim Powder	Multi-functional corn ingredient
Ingredient Statement:	Corn Fiber, Less than 0.50% of Sunflower Lecithin & DL-a-Tocopheryl acetate (Vitamin E).

Organoleptic Data: White to off-white powder, odorless, tasteless.

Physical Data:

Color L Value	L = 86.43	a = 1.99	b = 14.24
Viscosity	21320 cps	Temp at 30.0 °C, 4% solids Shear-thinning thixotropic gel	
Moisture	6.75 %		

Microbiological Data:

APC, (FDA BAM)	<10 cfu/g	
Yeast (FDA BAM)	<10 cfu/g	
Mold, (FDA BAM)	<10 cfu/g	
E. Coli (Petrifilm)	<10 cfu/g	
Coliform (Petrifilm)	<10 cfu/g	
Salmonella (FDA BAM)	Negative	/ 25g

Shelf Life: Two years if stored under cool dry conditions in a sealed container

Date of Manufacturing:	August 12, 2011
Expiration Date:	August 11, 2013
Date of Certification:	August 24, 2011

(b) (6)

Quality Assurance Manager
Jonathan Wall

Coa Corn Rev05.24.2010

000062

Z-TRIM INGREDIENTS

1011 Campus Drive,
Mundein, IL 60060,
(847) 549-6002,
www.ztrim.com

CERTIFICATE OF ANALYSIS

Country of Manufacture:	USA
Lot No:	(b) (4)
Z-Trim Powder	Multi-functional corn ingredient
Ingredient Statement:	Corn Fiber, Less than 0.50% of Sunflower Lecithin & DL-a-Tocopheryl acetate (Vitamin E).

Organoleptic Data:	White to off-white powder, odorless, tasteless.		
Physical Data:			
Color L Value	L = 87.32	a = 1.12	b = 14.22
Viscosity	22397 cps	Temp at 28.2 °C, 4% solids Shear-thinning thixotropic gel	
Moisture	7.39 %		
Microbiological Data:			
APC, (FDA BAM)	<10 cfu/g		
Yeast (FDA BAM)	<10 cfu/g		
Mold, (FDA BAM)	<10 cfu/g		
E. Coli (Petrifilm)	<10 cfu/g		
Coliform (Petrifilm)	<10 cfu/g		
Salmonella (FDA BAM)	Negative	/ 25g	

Shelf Life: Two years if stored under cool dry conditions in a sealed container

Date of Manufacturing:	August 15, 2011
Expiration Date:	August 14, 2013
Date of Certification:	August 29, 2011

(b) (6)

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Z-TRIM
INGREDIENTS

1011 Campus Drive,
Mundein, IL 60060,
(847) 549-6002,
www.ztrim.com

CERTIFICATE OF ANALYSIS

Country of Manufacture:	USA
Lot No:	(b) (4) 3
Z-Trim Powder	Multi-functional corn ingredient
Ingredient Statement:	Corn Fiber, Less than 0.50% of Sunflower Lecithin & DL-a-Tocopheryl acetate (Vitamin E).

Organoleptic Data:	White to off-white powder, odorless, tasteless.		
Physical Data:			
Color L Value	L = 87.32	a = 1.12	b = 14.22
Viscosity	22397 cps	Temp at 28.2 °C, 4% solids Shear-thinning thixotropic gel	
Moisture	7.39 %		
Microbiological Data:			
APC, (FDA BAM)	<10 cfu/g		
Yeast (FDA BAM)	<10 cfu/g		
Mold, (FDA BAM)	<10 cfu/g		
E. Coli (Petrifilm)	<10 cfu/g		
Coliform (Petrifilm)	<10 cfu/g		
Salmonella (FDA BAM)	Negative	/ 25g	

Shelf Life: Two years if stored under cool dry conditions in a sealed container

Date of Manufacturing:	August 15, 2011
Expiration Date:	August 14, 2013
Date of Certification:	August 29, 2011

(b) (6)

Quality Assurance Manager
Jonathan Wall

Coa Corn Rev05.24.2010

000064

Appendix A-5

SILLIKER
a Mérieux NutriSciences Company

SILLIKER, Inc.
Illinois Laboratory
1304 Halsted Street, Chicago Heights, IL 60411
877/ 777 6375 Fax 708/ 756 0049

CERTIFICATE OF ANALYSIS

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Received From:	Mundelein, IL
Received Date:	9/26/11
P.O.# / ID:	JW 9.24.2010
Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Composite 2011 Natural Corn
Desc. 2: Lot#/Sample Code: (b)

Laboratory ID: 328957969
Condition Rec'd: NORMAL
Temp Rec'd (°C): 19

Analyte — **Test Date** **Loc.**
Nutrition - Vegetables Package — 10/12/11

NUTRITIONAL ANALYSIS
Serving Size: 100 g
Household Measure: 100 g

LABEL ANALYTES		ANALYTICAL DATA PER 100g	ANALYTICAL DATA PER SERVING	ROUNDED DATA PER SERVING	% DAILY VALUE
Calories		376.5	376.5	380	
Calories from Fat		2.8	2.8	0	
Total Fat	(g)	0.32	0.32	0	0
Saturated Fat	(g)	<0.10	<0.10	0	0
Trans Fat	(g)	<0.10	<0.10	0	
Cholesterol	(mg)	N/A	N/A	N/A	N/A
Sodium	(mg)	573	573	570	24
Total Carbohydrate	(g)	93.4	93.4	93	31
Dietary Fiber	(g)	91.67	91.67	92	368
Sugars	(g)	<0.25	<0.25	0	
Protein (F=6.25)	(g)	<0.10	<0.10	0	
Vitamin A	(IU)	<5	<5		*
Vitamin C	(mg)	<1.0	<1.0		*
Calcium	(mg)	216	216		20
Iron	(mg)	1.3	1.3		8
CONTRIBUTING ANALYTES					
Moisture	(g)	5.39	5.39		
Ash	(g)	0.89	0.89		
Beta Carotene	(IU)	<5	<5		
Retinol	(IU)	<5	<5		
Vit A % Beta Carotene		*			

* Contains less than 2% of the Daily Value of this nutrient.

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Analytical Results

SUGAR PROFILE

Fructose	<0.25	(g/100g)	Glucose	<0.25	(g/100g)
Lactose	<0.25	(g/100g)	Maltose	<0.25	(g/100g)
Sucrose	<0.25	(g/100g)			

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Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

FAT ANALYSIS BY GC — Laboratory ID: 328957969

Fatty Acids	% Fatty Acid in Product (Weight/Weight Basis) Saturated	Cis MUFA	Cis PUFA	Trans	Conjugated	% as Triglyceride	% FA of Total FA
4:0 Butanoic (Butyric)						0.000	0.000
5:0 Pentanoic (Valeric)						0.000	0.000
6:0 Hexanoic (Caproic)						0.000	0.000
7:0 Heptanoic (Enanthic)						0.000	0.000
8:0 Octanoic (Caprylic)						0.000	0.000
9:0 Nonanoic (Pelargonic)						0.000	0.000
10:0 Decanoic (Capric)						0.000	0.000
11:0 Undecanoic						0.000	0.000
12:0 Dodecanoic (Lauric)						0.000	0.000
12:1 Dodecenoic						0.000	0.000
14:0 Tetradecanoic (Myristic)						0.000	0.000
14:1 trans-Tetradecenoic						0.000	0.000
14:1 Tetradecenoic (Myristoleic)						0.000	0.000
15:0 Pentadecanoic						0.000	0.000
15:1 Pentadecenoic						0.000	0.000
16:0 Hexadecanoic (Palmitic)	0.072					0.075	23.664
16:1 trans-Hexadecenoic						0.000	0.000
16:1 Hexadecenoic (Palmitoleic)						0.000	0.000
17:0 Heptadecanoic (Margaric)						0.000	0.000
17:1 Heptadecenoic (Margaroleic)						0.000	0.000
18:0 Octadecanoic (Stearic)	0.021					0.022	6.829
18:1 trans-Octadecenoic (incl. Elaidic)				0.007		0.007	2.368
18:1 Octadecenoic (incl. Oleic)		0.108				0.113	35.615
18:2 trans-Octadecadienoic						0.000	0.000
18:2 Octadecadienoic (Linoleic)			0.095			0.100	31.523
20:0 Eicosanoic (Arachidic)						0.000	0.000
18:3 trans-Octadecatrienoic						0.000	0.000
18:3 g-Linolenic						0.000	0.000
20:1 trans-Eicosenoic						0.000	0.000
20:1 Eicosenoic (incl. Gadoleic)						0.000	0.000
18:3 Octadecatrienoic (Linolenic)						0.000	0.000
21:0 Heneicosanoic						0.000	0.000
18:2 conj Linoleic						0.000	0.000
18:4 Octadecatetraenoic (Moroctic)						0.000	0.000
20:2 Eicosadienoic						0.000	0.000
20:3 5,8,11-Eicosatrienoic						0.000	0.000
22:0 Docosanoic (Behenic)						0.000	0.000
20:3 8,11,14-Eicosatrienoic (gamma)						0.000	0.000
22:1 trans-Docosaenoic (Brassidic)						0.000	0.000

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SILLIKER, Inc.
Illinois Laboratory
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CERTIFICATE OF ANALYSIS

COA No:	CHG-34819224-0
Supersedes:	None
COA Date	10/13/11
Page 4 of 4	

COPY TO:
Mr. Jonathan Wall
Z Trim Holdings Inc
1011 Campus Dr
Mundelein, IL 60060

ORIGINAL TO:
Ms. Lynda Carroll
Director of QA and Technical Services
Z Trim Holdings Inc.
1011 Campus Dr.
Mundelein, IL 60060

Received From:	Mundelein, IL
Received Date:	9/26/11
P.O.# / ID:	JW 9.24.2010
Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

FAT ANALYSIS BY GC Laboratory ID: 328957969

FAT ANALYSIS BY GC	% Fatty Acid in Product (Weight/Weight Basis)						
Fatty Acids	Saturated	Cis MUFA	Cis PUFA	Trans	Conjugated	% as Triglyceride	% FA of Total FA
22:1 Docosaenoic (Erucic)						0.000	0.000
20:3 11,14,17-Eicosatrienoic						0.000	0.000
20:4 Eicosatetraenoic (Arachidonic)						0.000	0.000
23:0 Tricosanoic						0.000	0.000
22:2 Docosadienoic						0.000	0.000
24:0 Tetracosanoic (Lignoceric)						0.000	0.000
20:5 Eicosapentaenoic						0.000	0.000
24:1 Tetracosaenoic (Nervonic)						0.000	0.000
22:3 Docosatrienoic						0.000	0.000
22:4 Docosatetraenoic						0.000	0.000
22:5 Docosapentaenoic						0.000	0.000
22:6 Docosahexaenoic						0.000	0.000
Total (g per 100g)	0.09	0.11	0.10	0.01	0.00	0.32	100.00
% of Total Fatty Acid Concentration	30.49	35.62	31.52	2.37	0.00		

FAT ANALYSIS BY GC - SUMMARY

Fat by Fatty Acid Profile:	0.32	(g/100g)	Total Polyunsaturated Fatty Acids:	0.10	(g/100g)
Total Saturated Fatty Acids:	0.09	(g/100g)	Total Trans Fatty Acids:	0.01	(g/100g)
Total Monounsaturated Fatty Acids:	0.11	(g/100g)	Total Conjugated Fatty Acids:	0.00	(g/100g)

(b) (6)

Randy Fleener Laboratory Director

Appendix A-6

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CERTIFICATE OF ANALYSIS

COA No:	CHG-34816375-0
Supersedes:	None
COA Date	10/11/11
Page 1 of 2	

COPY TO:
Mr. Jonathan Wall
Z Trim Holdings Inc
1011 Campus Dr
Mundelein, IL 60060

ORIGINAL TO:
Ms. Lynda Carroll
Director of QA and Technical Services
Z Trim Holdings Inc.
1011 Campus Dr.
Mundelein, IL 60060

Received From:	Mundelein, IL
Received Date:	10/3/11
P.O.# / ID:	JW 093010
Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Composite 2011 Natural Corn

Laboratory ID: 329080113
Condition Rec'd: NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
ICP MS Full Mineral Screen			EPA 3050/6020 USP730	10/11/11	BRN
Aluminum	26.6	ppm (w/w)			
Antimony	<0.010	ppm (w/w)			
Arsenic	0.116	ppm (w/w)			
Barium	2.12	ppm (w/w)			
Beryllium	<0.010	ppm (w/w)			
Bismuth	<0.020	ppm (w/w)			
Boron	1.26	ppm (w/w)			
Cadmium	<0.0010	ppm (w/w)			
Calcium	2260	ppm (w/w)			
Chromium	0.052	ppm (w/w)			
Cobalt	<0.010	ppm (w/w)			
Copper	<0.010	ppm (w/w)			
Iron	10.7	ppm (w/w)			
Lead	0.014	ppm (w/w)			
Lithium	<0.10	ppm (w/w)			
Magnesium	1030	ppm (w/w)			
Manganese	4.50	ppm (w/w)			
Mercury	<0.005	ppm (w/w)			
Molybdenum	0.522	ppm (w/w)			
Nickel	0.145	ppm (w/w)			
Phosphorus	225	ppm (w/w)			
Potassium	119	ppm (w/w)			
Selenium	<0.10	ppm (w/w)			
Silver	<0.020	ppm (w/w)			
Sodium	5690	ppm (w/w)			
Strontium	7.46	ppm (w/w)			
Thallium	<0.010	ppm (w/w)			
Thorium	<0.10	ppm (w/w)			
Tin	0.034	ppm (w/w)			
Titanium	0.042	ppm (w/w)			
Uranium	<0.010	ppm (w/w)			
Vanadium	0.010	ppm (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	CHG-34816375-0
Supersedes:	None
COA Date	10/11/11
Page 2 of 2	

COPY TO:
Mr. Jonathan Wall
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Received From:	Mundelein, IL
Received Date:	10/3/11
P.O.# / ID:	JW 093010
Location of Test: (except where noted) Chicago Heights, IL	

Analytical Results

Desc. 1: Composite 2011 Natural Corn

Laboratory ID: 329080113
Condition Rec'd: NORMAL
Temp Rec'd (°C): 19

Analyte	Result	Units	Method Reference	Test Date	Loc.
Zinc	9.66	ppm (w/w)			
Zirconium	<0.10	ppm (w/w)			

(b) (6)

Randy Fleener / Laboratory Director

Noted Test Locations: BRN-Silliker, JR Laboratories, 12-3871 North Fraser Way, Burnaby, BC V5J 5G6

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Appendix A-7

Corn Z Trim Shelf life Testing

Date Made	Lot #	L 84 to 94	a -0.8 to 3.00	b 7.0 to 23.0	Viscosity (cp) 20k- 40k	Granulation on 20 0.0.	L 84 to 94	a -0.8 to 3.00	b 7.0 to 23.0	Viscosity (cp) 20k- 40k	Granulation on 20 0.0 %	Moisture	Water Activity
		Original Sample Data					Shelf Life Data at 6 months						
2.3.10	979689	91.12	-10.00	14.58	36620	0.00	90.81	0.09	14.83	27053	0.00	5.85	0.296
2.7.10	979289	90.06	0.52	15.57	32800	0.00	89.52	0.64	15.73	29857	0.00	5.95	0.285
2.10.10	978989	91.79	0.01	12.96	34018	0.00	91.66	-0.40	12.81	32983	0.00	5.50	0.276
2.12.10	978789	90.07	0.38	14.80	34580	0.00	89.82	0.46	15.16	30322	0.00	5.65	0.306
2.15.10	978489	91.70	0.03	12.91	33180	0.00	91.66	-0.07	12.87	33520	0.00	6.20	0.339
2.18.10	978189	90.37	0.46	13.85	36054	0.00	90.25	0.54	14.04	32764	0.00	6.55	0.352
2.20.10	977989	92.47	-3.90	11.89	27008	0.00	92.81	-0.30	11.34	32681	0.00	6.40	0.346
2.23.10	977689	90.68	0.00	14.48	33680	0.00	90.29	0.15	15.02	29911	0.00	5.50	0.309
2.25..10	977489	93.92	-1.14	11.61	25580	0.00	94.13	0.97	10.04	21080	0.00	4.50	0.227
2.27.10	977289	91.72	-0.49	13.28	28980	0.00	91.07	0.00	13.62	28427	0.00	7.15	0.330
		Original Sample Data					Shelf Life Data at I year						
8.4.09	919590	87.59	1.84	15.74	30680	0.00	87.41	1.84	15.79	28888	0.00	7.65	0.418
8.06.09	919390	87.57	1.54	16.79	25160	0.00	87.25	1.53	16.98	28183	0.00	7.60	0.408
8.10.09	918990	91.07	0.1	12.37	27520	0.00	90.70	0.29	12.47	31727	0.00	7.10	0.416
8.17.09	918290	87.44	1.16	13.01	31540	0.00	87.42	1.09	13.28	27613	0.00	7.35	0.425
8.17.09	918290-B	89.89	0.72	14.92	27700	0.00	89.78	0.75	15.04	30137	0.00	6.70	0.407
8.20.09	917990	88.19	1.2	15.87	29000	0.00	87.89	1.41	16.26	28667	0.00	8.85	0.415
8.12.09	917890	89.21	1.08	15.58	30380	0.00	89.03	1.06	15.43	27093	0.00	7.85	0.403
8.24.09	917590	87.58	1.4	16.11	28040	0.00	87.21	1.42	16.46	30560	0.00	8.00	0.407
8.27.09	917290	89.63	0.87	16.36	28680	0.00	89.60	0.84	16.29	30227	0.00	7.50	0.413
8.31.09	916890	88.62	1.06	15.51	34427	0.00	86.82	1.60	17.08	31760	0.00	8.25	0.415
		Original Sample Data					Shelf Life Data at 1.5 years						
2.23.09	977690-A	87.68	0.36	22.29	24700	0.00	86.65	0.32	11.77	30933	0.00	8.25	0.435
2.23.09	977690-	88.32	0.2	11.71	25960	0.00	88.59	0.09	11.66	28679	0.00	6.60	0.425

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	B												
2.17.09	978290	88.5	0.69	17.39	31020	0.00	88.04	0.88	17.87	30613	0.00	6.75	0.417
2.19.09	978090	88.5	0.93	17.93	24280	0.00	88.03	0.94	18.16	30021	0.00	8.80	0.401
2.23.09	977690	86.49	1.3	21.3	26820	0.00	85.82	1.52	22.36	24747	0.00	8.20	0.420
2.25.09	977490	86.95	0.68	19.34	20127	0.00	86.43	1.33	19.37	21440	0.00	8.85	0.417
2.27.09	977290	89.82	0.92	14.81	26760	0.00	89.66	1.00	14.99	32358	0.00	8.55	0.423
3.02.09	969790	91.25	0.33	14.53	22600	0.00	90.79	0.46	14.76	24720	0.00	7.65	0.428
3.04.09	969590	90.35	0.67	13.45	30227	0.00	90.00	0.73	13.85	33853	0.00	7.50	0.415
3.06.09	969390	92.35	0.53	11.5	24100	0.00	92.04	0.60	11.85	29374	0.00	8.25	0.405
		Original Sample Data					**Shelf Life Data at 2 years**						
8.25.08	917491	90.25	-0.07	12.40	22900	0.00	90.61	0.27	12.56	22381	0.00	7.00	0.416
9.03.08	909691	91.66	-0.26	13.43	20400	0.00	88.84	0.42	16.43	21533	0.00	6.85	0.391
9.04.08	909591-B	92.63	-0.27	11.64	33000	0.00	92.47	-0.17	11.84	28111	0.00	8.20	0.389
9.05.08	909491	92.25	-0.14	13.09	28500	0.00	91.83	-0.90	13.15	26867	0.00	8.95	0.387
9.07.08	909291	90.29	-0.42	13.99	27000	0.00	89.97	0.50	14.63	23560	0.00	8.85	0.397
9.09.08	909091	91.88	-0.17	15.13	24200	0.00	90.66	0.08	16.29	19520	0.00	8.80	0.378
9.09.08	909091-B	89.22	0.44	15.37	26300	0.00	89.19	0.54	16.22	21944	0.00	8.65	0.393
9.06.08	908391	91.85	-0.04	14.26	20500	0.00	90.56	0.18	15.63	23067	0.00	7.95	0.396
9.17.08	908291	92.26	-0.02	12.75	21600	0.00	91.57	0.02	14.29	29013	0.00	7.90	0.388
9.23.08	907691	91.31	-0.60	12.46	21700	0.00	90.45	-0.37	14.56	23748	0.00	7.15	0.401
		Original Sample Data					**Shelf Life Data at 2.5 years**						
2.19.08	978091-B	89.77	-0.74	14.84	33200	0.00	89.08	1.01	16.03	24373	0.00	8.95	0.404
2.13.08	978691	92.14	-0.24	13.56	31800	0.00	91.98	0.15	14.43	28507	0.00	8.60	0.432
2.09.08	979091	92.86	-0.49	10.98	37100	0.00	92.30	-0.40	11.41	31173	0.00	7.60	0.372
2.06.08	979391	93.14	-0.10	10.53	31900	0.00	92.95	-0.01	11.87	26573	0.00	8.15	0.406
2.03.08	979691	92.26	0.29	12.53	34800	0.00	91.00	0.41	14.24	25893	0.00	8.60	0.411
2.03.08	979691-B	89.95	1.06	13.81	34500	0.00	89.56	1.00	14.94	26175	0.00	8.35	0.382
2.02.08	979791	92.25	0.16	12.19	31200	0.00	91.13	0.20	13.92	28439	0.00	7.35	0.417
2.24.08	977591	90.30	-0.03	13.29	40400	0.00	90.51	0.70	14.29	25867	0.00	7.65	0.381
2.21.08	977891	91.09	-0.37	13.26	40000	0.00	90.78	0.65	13.88	26693	0.00	8.40	0.408

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(b) (4)

[redacted]

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APPENDIX B

Efficacy Study on Meat & Poultry Products

Z Trim as Binders in Reduced Fat Burgers and Processed Meats

Robert G. Brannan, Ph.D.
Ohio University
October 01, 2010

STUDY OBJECTIVE

To evaluate the performance, based on texture analysis and sensory measurements, of Corn and Oat Z Trim as binders in reduced fat burgers and processed meat

MATERIALS AND METHODS

Preparation of Hydrated Corn and Oat Z Trim Isolates
Corn or Oat Z Trim was slowly added to distilled water in a Robot Coupe food processor to achieve 10% (w/w) corn or 20% (w/w) oat product isolates. Mixing was continued for an appropriate amount of time (usually 3-5 minutes) until all visible water was absorbed and a dough-like substance was formed. These were then stored in the refrigerator until use.

Preparation of Ground Meat Burgers

Beef burgers. Lean beef (eye of round) and beef fat were ground separately to 3/8 inch using a KitchenAid stand mixer. Ingredients (as shown in Table 1) were mixed for 3 min using a KitchenAid stand mixer paddle attachment. Beef mixtures were chilled and then reground through a 1/8 inch plate. Portions (100 g) were formed into balls which were turned into uniform patties using a mold. Patties were immediately frozen (-30 C) and stored in freezers until evaluation.

Turkey burgers. Light and dark turkey meats were ground once and turkey skin was ground twice to 1/8 inch using a KitchenAid stand mixer. Ingredients (as shown in Table 2) were mixed for 3 min using a KitchenAid stand mixer paddle attachment. Turkey mixtures were chilled and then 100 g portions were formed into balls which were turned into uniform patties using a mold. Patties were immediately frozen (-30 C) until analyzed.

Preparing burgers for evaluation. A day prior to analysis, beef or turkey patties were transferred to a refrigerator to thaw. On evaluation day, patties were placed on sheet trays and broiled in an electric oven for 4 min on each side. Burgers were then used immediately for sensory or objective analysis.

Table 1. Beef burger formulations.

	Gram ingredient per 100 grams formulation				
	Control	Using 10% Hydrated Corn Z Trim		Using 20% Hydrated Oat Z Trim	
Ingredients	22.3% Fat	12.3% Fat	2.3% Fat	12.3% Fat	2.3% Fat
Lean beef (3% fat)	80	80	80	80	80
Beef fat	20	10	0	10	0
Hydrated Z Trim	0	10	20	10	20
% Z Trim (w/w)	0	1	2	2	4

Table 2. Turkey burger formulations.

	Gram ingredient per 100 grams formulation				
	Control	Using 10% Hydrated Corn Z Trim		Using 20% Hydrated Oat Z Trim	
Ingredients	**7.1% Fat**	**4.7% Fat**	**2.3% Fat**	**4.7% Fat**	**2.3% Fat**
Light meat	55	55	55	55	55
Dark meat	32	32	32	32	32
Skin	13	6.5	0	6.5	0
Hydrated Z Trim	0	6.5	13	6.5	13
% Z Trim (w/w)	0	0.65	1.3	1.3	2.6

Preparation of Processed Meat (Frankfurters)

Following proportions for every 100 g formulation listed on Table 3, lean beef (eye of round) and beef fat were ground separately to 3/8 inch using a KitchenAid stand mixer. Hydrated Z Trim, nonfat dry milk (2.0 g), salt (1.5 g), phosphate (0.5 g), cure (0.4 g), sodium erythorbate (0.1 g), and seasoning (1.0 g) were then mixed thoroughly for approximately 1 min with the ground meat. The meat mixture and ice were emulsified by alternate additions of meat mix and ice in a Robot Coupe food processor. Frankfurters were formed by stuffing emulsified meat into prepared cellulose casings. Frankfurters were cooked for about 10 minutes in 180°F water up to an internal temperature of 160°F. These were then cooled to room temperature after which their casings were removed. Frankfurters were refrigerated until evaluation. On sampling days, frankfurters were prepared by boiling in hot water.

Table 3. Proportions of meat ingredients and Z Trim used in frankfurter formulations.

	Gram ingredient per 100 grams formulation				
	Control	Using 10% Hydrated Corn Z Trim		Using 20% Hydrated Oat Z Trim	
Ingredients	**25% Fat**	**12.5% Fat**	**1.7% Fat**	**12.5% Fat**	**1.7% Fat**
Lean beef	36.3	48.4	57.5	48.4	57.5
Beef fat	24.2	10.6	0	10.6	0
Hydrated Z Trim	0	1.5	3	1.5	3
% Z Trim (w/w)	0	0.15	0.30	0.30	0.60

Evaluations

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Yield. This was the weight of the samples after cooking compared to the weight of the samples before cooking. Measurements were taken on meat burgers only.

Texture evaluations. Texture was measured using a TA.XT2 Texture Analyzer (Texture Technologies Corp., Scarsdale, NY/Stable Micro Systems, Godalming, Surrey, UK) controlled via Texture Expert Software which recorded data and generated force-deformation curves.

For beef and turkey burgers, a ½" cylindrical probe at a crosshead speed of 1 mm/s was used to penetrate the patties. Burgers rested on a solid platform with a 5/8" hole through which the probe passed as it deployed. The work required to penetrate the burger (i.e., area under the force deformation curve) was used as an instrumental indicator of "tenderness".

With frankfurters, a 2" cylindrical probe at a crosshead speed of 10 mm/s was used to deform samples to a distance of 10 mm. A second "bite" was also performed, allowing for texture profile analysis. Force deformation curves were plotted and from these objective measurements for hardness, springiness, cohesiveness, gumminess, and chewiness were obtained.

Sensory Analysis. Ohio University's standing descriptive sensory panel evaluated the samples, according to the attributes listed on Table 4, using 15 cm unstructured line scales anchored with ratings of references.

Before evaluation, the panelists received roughly 11 additional hours of training on the specific attributes for this study. Standard sensory protocols were observed throughout training and testing.

Table 4. Sensory attributes tested.

Attribute	Definition
Burger Patties	
Hardness	The force required to compress a sample between incisors when a panelist places the food between molars and bites down evenly
Chewiness	The total amount of work necessary to chew a sample to a state ready for swallowing
Cohesiveness	The degree to which a sample deforms rather than crumbles, cracks, or breaks when a panelist places the sample between molars and compresses fully
Moisture release	The amount of moisture released after 3-4 chews
Oil mouth coating	The amount of oily mouth coating that is perceived in the mouth cavity after the sample has been swallowed or expectorated
Frankfurters	
Springiness	The degree to which the sample returns to its original shape
Overall hardness	The force required to bite through the sample
Chewy	The total amount of work necessary to chew a sample to a state ready for swallowing
Cohesiveness of mass	The degree to which a sample holds together in a mass after five chews
Grainy	The amount of particles in the mouth
Oily mouth coat	The amount of oil left on mouth surfaces

RESULTS AND DISCUSSIONS

Effects of Z Trim on Meat Burgers

Yield. For turkey burger, yields of Z Trim formulations were not statistically different ($\alpha = 0.05$) from that of the control. Analyses for beef burgers are summarized on Table 5. Similar to turkey, most Z Trim hamburger yields were not significantly different from that of the control ($\alpha = 0.05$). The only exception was the hamburger with 2% (w/w) of Corn Z Trim. When fat was removed and Corn Z Trim (10%, w/w) was added as a binder, yield increased slightly over the control.

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Table 5. Differences in yield of hamburger samples.

Treatment	Amount Z Trim (%, w/w)	Yield*
Control, 22.3% Fat	0	0.64 ± 0.02 ab
Corn Z Trim		
12.3% Fat	1	0.65 ± 0.01 ab

2.3% Fat	2	0.72 ± 0.04 c
Oat Z Trim		
12.3% Fat	2	0.62 ± 0.03 a
2.3% Fat	4	0.67 ± 0.02 bc

* Ratio of cooked weight/uncooked weight; treatments coded with the same letter were not significantly difference at α = 0.05; measurements were alphanumerically coded in ascending order with lowest values assigned an "a". Three replications were performed for each treatment, with yield calculated from five patties within each replication.

Tenderness. Results of regression analysis on instrumental tenderness measurements of meat burgers are summarized in Tables 6 and 7. The tenderness of most burger formulations containing Z Trim did not significantly differ from that of the control (α = 0.05). The exceptions were the burgers containing the maximum amounts of Corn Z Trim studied. Hamburgers and turkey burgers with 2% and 1.3% (w/w) Corn Z Trim, respectively, were measured to be "more tender" than the control. This difference may, in part, be attributed to the lower meat (i.e., beef fat or turkey skin) levels of the treatments. However, it should be noted that burgers containing the maximum amounts of Oat Z Trim (i.e., 4%, w/w, for beef and 2.3%, w/w, for turkey) did not significantly differ from the control in terms of instrumental tenderness measurements.

Table 6. Differences in instrumental texture measurements of hamburgers.

Treatment	Amount Z Trim (%, w/w)	Tenderness*
Control, 22.3% Fat	0	1070 ± 278 bc
Corn Z Trim		
12.3% Fat	1	928 ± 144 b
2.3% Fat	2	683 ± 70 a
Oat Z Trim		
12.3% Fat	2	1215 ± 290 c
2.3% Fat	4	1019 ± 245 b

* Area under the force deformation curve measured and plotted using the ½" cylindrical probe of a TA.XT2 Texture Analyzer (Texture Technologies Corp., Scarsdale, NY/Stable Micro Systems, Godalming, Surrey, UK), deployed at a crosshead speed of 1 mm/s; values followed with the same letters were not significantly different ($p < 0.05$); values coded with the same letter were not significantly difference at α = 0.05; measurements were alphanumerically coded in ascending order with lowest values assigned an "a". Three replications were performed for each treatment, with area calculated from five patties within each replication.

Table 7. Differences in instrumental texture measurements of turkey burgers.

Treatment	Amount Z Trim (%, w/w)	Tenderness*
Control, 7.1% Fat	0	1226 ± 200 bc
Corn Z Trim		
4.7% Fat	0.65	1155 ± 132 bc
2.3% Fat	1.30	1075 ± 221 a
Oat Z Trim		
4.7% Fat	1.30	1281 ± 135 c
2.3% Fat	2.60	1199 ± 280 bc

* Area under the force deformation curve measured and plotted using the ½" cylindrical probe of a TA.XT2 Texture Analyzer (Texture Technologies Corp., Scarsdale, NY/Stable Micro Systems, Godalming, Surrey, UK), deployed at a crosshead speed of 1 mm/s; values followed with the same letters were not significantly different ($p < 0.05$); values coded with the same letter were not significantly difference at $\alpha = 0.05$; measurements were alphanumerically coded in ascending order with lowest values assigned an "a". Three replications were performed for each treatment, with area calculated from five patties within each replication.

Sensory evaluation. Analysis of sensory data indicated that trained panelists could not differentiate Z Trim treatments from the control ($\alpha = 0.05$) and amongst each other in all attributes tested except for "hardness" in hamburger. Panelists determined that beef burgers with Corn Z Trim were slightly "more tender" than those with Oat Z Trim and the control, which exhibited no difference from each other. This difference, detected in beef and not in turkey burgers, partly corresponded with observed instrumental measures discussed above. Either way, "less hard/more tender" patties may be considered "desirable" by business-to-business customers especially if all other texture characteristics remain the same from a human perspective.

Table 8. Differences in sensory hardness ratings of hamburger samples.

Treatment	Amount Z Trim (%, w/w)	Hardness Rating*
Control, 22.3% Fat	0	6.21 ± 1.02 b
Corn Z Trim		
12.3% Fat	1	5.12 ± 0.99 a
2.3% Fat	2	5.00 ± 1.13 a
Oat Z Trim		
12.3% Fat	3	6.39 ± 1.30 b
2.3% Fat	4	5.73 ± 1.11 ab

* Ratings based on 15 cm unstructured line scale; values followed with the same letters were not significantly different ($p < 0.05$). n=10 (Five panelists sampled two patties from within a treatment).

Effect of Z Trim on Processed Meat

Instrumental texture profile. Regression analyses on Texture Analyzer data are summarized in Table 9. Results indicated that Oat Z Trim formulations were not significantly different from the control ($\alpha = 0.05$) on all texture profile characteristics except cohesiveness. On the other hand, almost all of the Corn Z Trim formulations were significantly different ($\alpha = 0.05$) except in springiness.

000079

Table 9. Results of regression analysis on frankfurter texture instrumental data.

Treatment	Amount Z Trim (%, w/w)	Texture Profile*				
		Hardness**	Springiness**	Cohesiveness**	Gumminess**	Chewiness**
Control, 25% Fat	0	1207 ± 215 a	0.87 ± 0.03 a	0.82 ± 0.05 a	988 ± 167 a	869 ± 160 a
Corn Z Trim						
12.5% Fat	0.15	2907 ± 2279 b	0.85 ± 0.05 a	0.81 ± 0.05 a	2335 ± 1780 b	1995 ± 1487 b
1.7% Fat	0.30	2855 ± 1513 b	0.86 ± 0.06 a	0.86 ± 0.01 b	2447 ± 1269 b	2149 ± 1228 b
Oat Z Trim						
12.5% Fat	0.30	608 ± 202 a	0.84 ± 0.07 a	0.86 ± 0.03 b	521 ± 171 a	445 ± 169 a
1.7% Fat	0.60	1169 ± 425 a	0.85 ± 0.03 a	0.84 ± 0.01 ab	895 ± 169 a	821 ± 231 a
Significance		0.0	0.467	0.0	0.0	0.0

* Measured using the 2" cylindrical probe of a TA.XT2 Texture Analyzer (Texture Technologies Corp., Scarsdale, NY/Stable Micro Systems, Godalming, Surrey, UK), deployed at a crosshead speed of 10 mm/s.

** Treatments coded with the same letter were not significantly difference at $\alpha = 0.05$; measurements were alphanumerically coded in ascending order with lowest values assigned an "a". Means represent 5 trials from 3 replicates (n=15).

Sensory evaluation. Analysis of sensory data indicated that trained panelists could not differentiate Z Trim treatments from the control ($\alpha = 0.05$) and amongst each other in all attributes except for hardness. These results demonstrated that, despite differences in instrumental measurements, highly trained human subjects were unable to detect textural effects of Z Trim on frankfurters. The exception was "hardness" (Table 10) where formulations seemed more "tender" than the control except for the one containing 0.30% Oat Z Trim. The general observations in this section echoed those of other studies which demonstrated that, in cases where instrumental measurements do not correspond with trained panel data, the former is much more sensitive than the latter and may not have any practical value when evaluating human responses.

Table 10. Differences in sensory hardness ratings of frankfurter samples.

Treatment	Amount Z Trim (%, w/w)	Hardness Rating*
Control, 25% Fat	0	6.30 ± 1.36 c
Corn Z Trim		
12.5% Fat	0.15	4.04 ± 1.55 ab
1.7% Fat	0.30	3.14 ± 1.38 a
Oat Z Trim		
12.5% Fat	0.30	5.00 ± 1.36 bc
1.7% Fat	0.60	3.66 ± 2.02 ab

* Ratings based on 15 cm unstructured line scale; values followed with the same letters were not significantly different ($p < 0.05$). n=10 (Five panelists sampled two patties from within a treatment).

Appendix 1. Yield of turkey burger samples.

Treatment	Amount Z Trim (%, w/w)	Yield*
Control, 22.3% Fat	0	0.79 ± 0.03
Corn Z Trim		
12.3% Fat	0.65	0.71 ± 0.07
2.3% Fat	1.30	0.77 ± 0.05
Oat Z Trim		
12.3% Fat	1.30	0.78 ± 0.01
2.3% Fat	2.60	0.73 ± 0.01

*Ratio of cooked weight/uncooked weight; none of the treatments were significantly differenct from one another at $\alpha = 0.05$; Three replications were performed for each treatment, with yield calculated from five patties within each replication.

Appendix 2: Hamburger data sorted by replication

Descriptive Statistics – Hamburger Instrumental Data

	Replication	TRT	Mean	Std. Deviation	N
AREA Hamburger	1	Control	1397.8000	126.04444	5
		Corn_100	640.2600	48.87201	5
		Corn_50	950.5400	96.54635	5
		Oat_100	784.2600	85.71734	5
		Oat_50	908.8600	204.42044	5
		Total	936.3440	283.60751	25
	2	Control	984.3800	114.14117	5
		Corn_100	705.9400	78.41207	5
		Corn_50	1013.8000	62.18275	5
		Oat_100	1193.8000	121.29798	5
		Oat_50	1422.6000	192.50662	5
		Total	1064.1040	267.06763	25
	3	Control	829.0400	159.83319	5
		Corn_100	703.7000	74.77075	5
		Corn_50	822.2000	190.16581	5
		Oat_100	1080.9400	289.61830	5
		Oat_50	1313.6000	182.04477	5
		Total	949.8960	284.47084	25
	Total	Control	1070.4067	278.01239	15
		Corn_100	683.3000	70.92059	15
		Corn_50	928.8467	144.59540	15
		Oat_100	1019.6667	249.45990	15
		Oat_50	1215.0200	290.40051	15
		Total	983.4480	280.69932	75
L_color Hamburger	1	Control	45.8600	0.97108	5
		Corn_100	48.5400	1.72134	5
		Corn_50	48.1600	1.25817	5
		Oat_100	51.4200	1.11669	5

000082

		Oat_50	50.0200	1.21532	5
		Total	48.8000	2.23812	25
	2	Control	46.6400	1.36492	5
		Corn_100	50.9800	1.52217	5
		Corn_50	47.4000	1.28647	5
		Oat_100	50.6200	3.13321	5
		Oat_50	46.1600	1.49766	5
		Total	48.3600	2.70062	25
	3	Control	50.0400	2.10309	5
		Corn_100	49.2600	1.08766	5
		Corn_50	47.3200	1.59437	5
		Oat_100	50.1600	1.38130	5
		Oat_50	44.6200	2.37634	5
		Total	48.2800	2.67986	25
	Total	Control	47.5133	2.36518	15
		Corn_100	49.5933	1.72315	15
		Corn_50	47.6267	1.34349	15
		Oat_100	50.7333	1.99917	15
		Oat_50	46.9333	2.86423	15
		Total	48.4800	2.52431	75
a_color Hamburger	1	Control	8.1400	1.15022	5
		Corn_100	7.3800	1.55628	5
		Corn_50	6.6600	1.43283	5
		Oat_100	7.2400	0.82037	5
		Oat_50	7.6600	0.39115	5
		Total	7.4160	1.16250	25
	2	Control	9.9400	4.59162	5
		Corn_100	7.8600	1.54532	5
		Corn_50	8.2200	2.04255	5
		Oat_100	7.5800	1.00349	5
		Oat_50	11.7400	7.39141	5
		Total	9.0680	4.05480	25
	3	Control	6.5000	0.80312	5

000083

		Corn_100	8.2400	0.55946	5
		Corn_50	7.5600	1.15888	5
		Oat_100	7.7400	0.88204	5
		Oat_50	7.1600	3.87724	5
		Total	7.4400	1.83689	25
	Total	Control	8.1933	2.94969	15
		Corn_100	7.8267	1.26348	15
		Corn_50	7.4800	1.61254	15
		Oat_100	7.5200	0.86537	15
		Oat_50	8.8533	4.94540	15
		Total	7.9747	2.73328	75
b_color Hamburger	1	Control	10.6600	1.26807	5
		Corn_100	8.2000	4.22078	5
		Corn_50	10.6000	0.85732	5
		Oat_100	11.4400	0.50299	5
		Oat_50	10.7800	1.44810	5
		Total	10.3360	2.24349	25
	2	Control	10.7800	1.58019	5
		Corn_100	10.9800	1.21326	5
		Corn_50	11.5400	0.89889	5
		Oat_100	13.9200	2.28408	5
		Oat_50	10.3400	1.42408	5
		Total	11.5120	1.91536	25
	3	Control	10.6400	0.97622	5
		Corn_100	10.3400	0.54129	5
		Corn_50	10.4400	0.75033	5
		Oat_100	12.6000	1.56365	5
		Oat_50	10.8600	2.77903	5
		Total	10.9760	1.64805	25
	Total	Control	10.6933	1.20384	15
		Corn_100	9.8400	2.66614	15
		Corn_50	10.8600	0.92412	15
		Oat_100	12.6533	1.83337	15

000084

		Mean	Std. Deviation	N
	Oat_50	10.6600	1.85503	15
	Total	10.9413	1.98427	75

Descriptive Statistics – Hamburger Sensory Analysis

	Replication	TRT	Mean	Std. Deviation	N
HARDNESS Hamburger Sensory	1	CONTROL	6.3800	1.27945	5
		CORN_100	4.4500	0.68557	4
		CORN_50	5.4200	1.23369	5
		OAT_100	5.5800	0.37014	5
		OAT_50	6.3000	1.24700	5
		Total	5.6750	1.17260	24
	2	CONTROL	6.0400	0.80187	5
		CORN_100	5.4200	1.29885	5
		CORN_50	4.8200	0.67971	5
		OAT_100	5.8800	1.60997	5
		OAT_50	6.4800	1.50566	5
		Total	5.7280	1.26870	25
	Total	CONTROL	6.2100	1.02247	10
		CORN_100	4.9889	1.13186	9
		CORN_50	5.1200	0.99085	10
		OAT_100	5.7300	1.11260	10
		OAT_50	6.3900	1.30678	10
		Total	5.7020	1.21011	49
CHEWY Hamburger Sensory	1	CONTROL	20.2000	8.28855	5
		CORN_100	22.5000	12.34234	4
		CORN_50	21.4000	6.80441	5
		OAT_100	23.8000	6.97854	5
		OAT_50	21.4000	6.46529	5
		Total	21.8333	7.56230	24
	2	CONTROL	20.4000	8.56154	5
		CORN_100	21.0000	5.47723	5

000085

		CORN_50	16.4000	4.33590	5
		OAT_100	23.6000	8.70632	5
		OAT_50	19.6000	3.04959	5
		Total	20.2000	6.33772	25
	Total	CONTROL	20.3000	7.94495	10
		CORN_100	21.6667	8.52936	9
		CORN_50	18.9000	5.98981	10
		OAT_100	23.7000	7.43938	10
		OAT_50	20.5000	4.85913	10
		Total	21.0000	6.94022	49
COHESIVE Hamburger Sensory	1	CONTROL	6.4400	1.27004	5
		CORN_100	5.8000	1.19164	4
		CORN_50	6.4200	1.83494	5
		OAT_100	6.4600	2.43064	5
		OAT_50	6.6400	1.86360	5
		Total	6.3750	1.66087	24
	2	CONTROL	6.3600	2.11376	5
		CORN_100	6.7400	1.62727	5
		CORN_50	7.4600	1.41527	5
		OAT_100	6.9400	1.51261	5
		OAT_50	6.5800	1.81714	5
		Total	6.8160	1.61159	25
	Total	CONTROL	6.4000	1.64452	10
		CORN_100	6.3222	1.44981	9
		CORN_50	6.9400	1.63924	10
		OAT_100	6.7000	1.92527	10
		OAT_50	6.6100	1.73554	10
		Total	6.6000	1.63401	49
MOISTURE RELEASE Hamburger Sensory	1	CONTROL	2.8400	0.86487	5
		CORN_100	3.4000	1.43062	4
		CORN_50	3.0200	0.87006	5
		OAT_100	3.4200	1.68731	5
		OAT_50	2.2600	0.42778	5

000086

		Total	2.9708	1.11608	24
	2	CONTROL	2.9400	0.70214	5
		CORN_100	2.9600	0.96073	5
		CORN_50	4.0800	0.68337	5
		OAT_100	4.0000	0.88318	5
		OAT_50	3.0000	0.54772	5
		Total	3.3960	0.88482	25
	Total	CONTROL	2.8900	0.74454	10
		CORN_100	3.1556	1.13260	9
		CORN_50	3.5500	0.92526	10
		OAT_100	3.7100	1.30593	10
		OAT_50	2.6300	0.60562	10
		Total	3.1878	1.01707	49
OIILY_MOUTH COATING Hamburger Sensory	1	CONTROL	3.9200	1.09864	5
		CORN_100	3.6500	1.37961	4
		CORN_50	4.3000	1.02225	5
		OAT_100	3.3800	1.16705	5
		OAT_50	4.1400	1.27593	5
		Total	3.8875	1.12995	24
	2	CONTROL	4.3000	0.87750	5
		CORN_100	4.5000	1.14237	5
		CORN_50	5.0000	0.73144	5
		OAT_100	3.7800	1.26372	5
		OAT_50	3.8800	1.56429	5
		Total	4.2920	1.14561	25
	Total	CONTROL	4.1100	0.95853	10
		CORN_100	4.1222	1.25178	9
		CORN_50	4.6500	0.91561	10
		OAT_100	3.5800	1.16600	10
		OAT_50	4.0100	1.35273	10
		Total	4.0939	1.14444	49

000087

Appendix 3: Turkey burger data sorted by replication

Descriptive Statistics – Turkey Burger Instrumental Data

	Replication	TRT	Mean	Std. Deviation	N
AREA Turkey Burger	1	Control	1116.8000	231.74059	5
		Corn_100	1031.2800	142.46084	5
		Corn_50	1215.0000	156.02564	5
		Oat_100	1235.4600	205.29249	5
		Oat_50	1213.6000	128.11635	5
		Total	1162.4280	179.99945	25
	2	Control	1314.8000	167.56103	5
		Corn_100	1148.3000	285.99423	5
		Corn_50	1086.5400	115.40086	5
		Oat_100	1035.9000	92.65824	5
		Oat_50	1325.0000	126.36257	5
		Total	1182.1080	197.83734	25
	3	Control	1248.0000	184.65779	5
		Corn_100	1046.7400	242.59344	5
		Corn_50	1166.0000	117.11746	5
		Oat_100	1326.1400	412.71200	5
		Oat_50	1306.8000	150.99404	5
		Total	1218.7360	246.79131	25
	Total	Control	1226.5333	200.88763	15
		Corn_100	1075.4400	221.06388	15
		Corn_50	1155.8467	132.97141	15
		Oat_100	1199.1667	280.90723	15
		Oat_50	1281.8000	135.33936	15
		Total	1187.7573	208.58332	75
L_color Turkey Burger	1	Control	65.7000	2.44643	5
		Corn_100	67.3800	2.62336	5
		Corn_50	64.7600	1.89947	5
		Oat_100	66.0400	3.07050	5

000088

		Oat_50	62.3400	4.06239	5
		Total	65.2440	3.16216	25
	2	Control	60.5600	1.46219	5
		Corn_100	62.5600	2.86409	5
		Corn_50	60.5200	1.62696	5
		Oat_100	60.7400	3.31858	5
		Oat_50	65.3200	1.57861	5
		Total	61.9400	2.82710	25
	3	Control	67.0000	1.82071	5
		Corn_100	66.4200	1.79081	5
		Corn_50	62.6000	2.25942	5
		Oat_100	62.3800	3.12202	5
		Oat_50	63.6600	1.80638	5
		Total	64.4120	2.82906	25
	Total	Control	64.4200	3.39878	15
		Corn_100	65.4533	3.14253	15
		Corn_50	62.6267	2.54094	15
		Oat_100	63.0533	3.72614	15
		Oat_50	63.7733	2.81995	15
		Total	63.8653	3.22899	75
a_color Turkey Burger	1	Control	4.0800	0.81670	5
		Corn_100	5.0000	1.83030	5
		Corn_50	5.7000	2.15754	5
		Oat_100	4.8800	1.17771	5
		Oat_50	4.8400	1.98066	5
		Total	4.9000	1.61452	25
	2	Control	6.1400	1.07145	5
		Corn_100	6.7600	1.43283	5
		Corn_50	6.5400	0.74364	5
		Oat_100	5.3200	0.88713	5
		Oat_50	4.2800	1.22352	5
		Total	5.8080	1.36593	25
	3	Control	3.8200	1.54822	5

000089

		Corn_100	3.4400	1.91911	5
		Corn_50	5.9200	2.45906	5
		Oat_100	4.3000	1.17686	5
		Oat_50	4.8000	1.65831	5
		Total	4.4560	1.86706	25
	Total	Control	4.6800	1.53539	15
		Corn_100	5.0667	2.13698	15
		Corn_50	6.0533	1.83064	15
		Oat_100	4.8333	1.09718	15
		Oat_50	4.6400	1.55048	15
		Total	5.0547	1.70352	75
b_color Turkey Burger	1	Control	16.2600	0.70214	5
		Corn_100	17.4800	1.18617	5
		Corn_50	18.2000	1.76352	5
		Oat_100	17.8000	3.17726	5
		Oat_50	15.7800	1.50566	5
		Total	17.1040	1.94668	25
	2	Control	19.2000	1.63248	5
		Corn_100	16.8200	3.41423	5
		Corn_50	18.9000	1.50333	5
		Oat_100	17.1800	1.95627	5
		Oat_50	17.0600	2.52052	5
		Total	17.8320	2.34818	25
	3	Control	15.2400	1.74442	5
		Corn_100	17.6400	1.33342	5
		Corn_50	17.6800	2.04377	5
		Oat_100	17.7000	2.06882	5
		Oat_50	14.9800	2.31668	5
		Total	16.6480	2.18119	25
	Total	Control	16.9000	2.18893	15
		Corn_100	17.3133	2.09178	15
		Corn_50	18.2600	1.73073	15
		Oat_100	17.5600	2.29776	15

000090

	Oat_50	15.9400	2.18691	15
	Total	17.1947	2.19119	75

Descriptive Statistics – Turkey Burger Sensory Analysis

	Replication	TRT	Mean	Std. Deviation	N
HARDNESS Turkey Burger Sensory	1	CONTROL	5.3500	1.55885	4
		CORN_100	6.0250	1.33010	4
		CORN_50	6.8000	1.25167	4
		OAT_100	5.6000	1.42127	4
		OAT_50	6.6750	1.15289	4
		Total	6.0900	1.33570	20
	2	CONTROL	5.4850	0.97685	4
		CORN_100	6.1750	1.32759	4
		CORN_50	6.7250	1.61529	4
		OAT_100	5.7000	1.51217	4
		OAT_50	7.0750	1.65806	4
		Total	6.2320	1.41936	20
	Total	CONTROL	5.4175	1.20648	8
		CORN_100	6.1000	1.23288	8
		CORN_50	6.7625	1.33838	8
		OAT_100	5.6500	1.35962	8
		OAT_50	6.8750	1.33924	8
		Total	6.1610	1.36228	40
CHEWY Turkey Burger Sensory	1	CONTROL	13.2500	3.77492	4
		CORN_100	16.0000	4.96655	4
		CORN_50	16.5000	6.55744	4
		OAT_100	15.7500	5.56028	4
		OAT_50	16.2500	3.77492	4
		Total	15.5500	4.63936	20
	2	CONTROL	16.7500	4.42531	4
		CORN_100	18.5000	6.13732	4

000091

		CORN_50	14.7500	1.25831	4
		OAT_100	15.5000	4.20317	4
		OAT_50	19.2500	6.50000	4
		Total	16.9500	4.67327	20
	Total	CONTROL	15.0000	4.24264	8
		CORN_100	17.2500	5.33854	8
		CORN_50	15.6250	4.47014	8
		OAT_100	15.6250	4.56501	8
		OAT_50	17.7500	5.17549	8
		Total	16.2500	4.65061	40
COHESIVE Turkey Burger Sensory	1	CONTROL	7.4500	1.44338	4
		CORN_100	6.5500	2.64512	4
		CORN_50	6.7000	2.48328	4
		OAT_100	7.4250	2.37960	4
		OAT_50	8.1750	0.09574	4
		Total	7.2600	1.91432	20
	2	CONTROL	8.6500	0.51962	4
		CORN_100	6.4250	1.70171	4
		CORN_50	8.7500	0.56862	4
		OAT_100	8.4500	0.61373	4
		OAT_50	8.1500	1.36748	4
		Total	8.0850	1.29423	20
	Total	CONTROL	8.0500	1.19164	8
		CORN_100	6.4875	2.06012	8
		CORN_50	7.7250	1.99553	8
		OAT_100	7.9375	1.69953	8
		OAT_50	8.1625	0.89752	8
		Total	7.6725	1.66610	40
MOISTURE RELEASE Turkey Burger Sensory	1	CONTROL	3.6500	1.65429	4
		CORN_100	4.5500	1.41067	4
		CORN_50	3.5500	1.90526	4
		OAT_100	2.9250	1.21484	4
		OAT_50	4.2750	1.43614	4

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		Total	3.7900	1.49099	20
	2	CONTROL	4.2250	1.32256	4
		CORN_100	3.5000	0.98319	4
		CORN_50	3.9250	1.55858	4
		OAT_100	4.7250	1.44770	4
		OAT_50	3.5500	1.75214	4
		Total	3.9850	1.35851	20
	Total	CONTROL	3.9375	1.42020	8
		CORN_100	4.0250	1.25783	8
		CORN_50	3.7375	1.62387	8
		OAT_100	3.8250	1.56730	8
		OAT_50	3.9125	1.53291	8
		Total	3.8875	1.41134	40
OIILY_MOUTH COATING Turkey Burger Sensory	1	CONTROL	3.3750	1.37689	4
		CORN_100	3.2750	1.50638	4
		CORN_50	3.8250	0.86554	4
		OAT_100	3.0500	1.27148	4
		OAT_50	3.3500	1.26095	4
		Total	3.3750	1.16161	20
	2	CONTROL	3.8000	0.57735	4
		CORN_100	3.2750	1.38414	4
		CORN_50	3.0250	1.23390	4
		OAT_100	3.5250	0.91788	4
		OAT_50	3.0750	0.64485	4
		Total	3.3400	0.93943	20
	Total	CONTROL	3.5875	1.00348	8
		CORN_100	3.2750	1.33924	8
		CORN_50	3.4250	1.07537	8
		OAT_100	3.2875	1.05754	8
		OAT_50	3.2125	0.93875	8
		Total	3.3575	1.04290	40

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Appendix 4: Frankfurter data sorted by replication

Descriptive Statistics -- Frankfurter Texture Profile Analysis (TPA)

	Replication	TRT	Mean	Std. Deviation	N
SPRINGY Frankfurter TPA	1	Control	0.8710	0.01654	5
		Corn 100	0.8545	0.09281	4
		Corn 50	0.8298	0.05029	4
		Oat 100	0.8287	0.03980	3
		Oat 50	0.8218	0.09995	4
		Total	0.8433	0.06293	20
	2	Control	0.8856	0.01935	5
		Corn 100	0.8563	0.03250	4
		Corn 50	0.8627	0.06801	3
		Oat 100	0.8820	0.00872	3
		Oat 50	0.8528	0.03103	4
		Total	0.8683	0.03388	19
	3	Control	0.8753	0.06346	4
		Corn 100	0.8583	0.06087	3
		Corn 50	0.8600	0.06755	3
		Oat 100	0.8503	0.02055	3
		Oat 50	0.8423	0.09699	3
		Total	0.8584	0.05796	16
	Total	Control	0.8774	0.03423	14
		Corn 100	0.8562	0.06037	11
		Corn 50	0.8487	0.05614	10
		Oat 100	0.8537	0.03256	9
		Oat 50	0.8386	0.07325	11
		Total	0.8563	0.05314	55
COHESIVE Frankfurter TPA	1	Control	0.8278	0.02318	5
		Corn 100	0.8705	0.02114	4
		Corn 50	0.8038	0.05479	4

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		Oat 100	0.8303	0.04875	3
		Oat 50	0.8578	0.02825	4
		Total	0.8379	0.04027	20
	2	Control	0.8086	0.02726	5
		Corn 100	0.8465	0.01834	4
		Corn 50	0.8083	0.05330	3
		Oat 100	0.8497	0.02098	3
		Oat 50	0.8515	0.03541	4
		Total	0.8321	0.03498	19
	3	Control	0.8242	0.00907	4
		Corn 100	0.8723	0.00153	3
		Corn 50	0.8203	0.05832	3
		Oat 100	0.8297	0.00874	3
		Oat 50	0.8693	0.02139	3
		Total	0.8420	0.03291	16
	Total	Control	0.8199	0.02218	14
		Corn 100	0.8623	0.01981	11
		Corn 50	0.8101	0.04942	10
		Oat 100	0.8366	0.02864	9
		Oat 50	0.8586	0.02761	11
		Total	0.8371	0.03600	55
GUMMY Frankfurter TPA	1	Control	1025.4362	107.04706	5
		Corn 100	2801.0800	1823.45809	4
		Corn 50	2873.6350	2848.39964	4
		Oat 100	1094.2520	534.97858	3
		Oat 50	572.7665	183.75104	4
		Total	1669.9931	1683.26821	20
	2	Control	1050.2282	113.57186	5
		Corn 100	2373.0275	1143.02735	4
		Corn 50	2448.9710	357.26740	3
		Oat 100	918.3913	221.59751	3
		Oat 50	472.0843	167.92603	4
		Total	1407.0355	950.09006	19

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	3	Control	863.7300	243.83249	4
		Corn 100	2074.0207	802.07016	3
		Corn 50	1505.8000	573.99769	3
		Oat 100	895.7517	169.14760	3
		Oat 50	519.5527	211.51321	3
		Total	1152.5184	679.50386	16
	Total	Control	988.0887	167.31696	14
		Corn 100	2447.1356	1269.71984	11
		Corn 50	2335.8853	1780.02987	10
		Oat 100	969.4650	315.96653	9
		Oat 50	521.6419	171.94717	11
		Total	1428.6151	1212.60504	55
CHEWY Frankfurter TPA	1	Control	893.3042	96.09756	5
		Corn 100	2509.8818	1785.95996	4
		Corn 50	2424.0390	2381.97248	4
		Oat 100	893.6707	397.92816	3
		Oat 50	483.1470	189.72375	4
		Total	1440.7902	1478.90324	20
	2	Control	929.0436	88.51073	5
		Corn 100	2055.1275	1063.68282	4
		Corn 50	2097.2890	143.00685	3
		Oat 100	810.5300	199.85964	3
		Oat 50	406.0475	161.20850	4
		Total	1221.7566	826.61644	19
	3	Control	764.9907	260.22847	4
		Corn 100	1793.8973	774.13838	3
		Corn 50	1320.6993	604.46665	3
		Oat 100	759.6673	127.59222	3
		Oat 50	449.0947	211.17874	3
		Total	1001.8774	619.58281	16
	Total	Control	869.4073	160.69109	14
		Corn 100	2149.2481	1228.66947	11
		Corn 50	1995.0121	1487.90575	10

000096

		Oat 100	821.2893	238.90302	9
		Oat 50	445.8238	169.43305	11
		Total	1237.4403	1065.73766	55
HARDNESS Frankfurter TPA	1	Control	1239.7774	142.47276	5
		Corn 100	3252.7355	2166.43078	4
		Corn 50	3601.8438	3638.00548	4
		Oat 100	1346.0720	737.00749	3
		Oat 50	671.1368	221.89588	4
		Total	2016.9984	2088.46548	20
	2	Control	1302.5348	168.13705	5
		Corn 100	2817.5998	1390.94582	4
		Corn 50	3054.0630	612.33579	3
		Oat 100	1080.8057	257.54537	3
		Oat 50	554.2975	194.65478	4
		Total	1705.5194	1169.04863	19
	3	Control	1047.1183	291.39932	4
		Corn 100	2377.0510	919.02248	3
		Corn 50	1833.6040	653.40659	3
		Oat 100	1080.8223	208.86907	3
		Oat 50	597.3370	245.28007	3
		Total	1365.9323	781.07982	16
	Total	Control	1207.1453	215.24040	14
		Corn 100	2855.6813	1513.18645	11
		Corn 50	2907.0376	2279.41739	10
		Oat 100	1169.2333	425.29336	9
		Oat 50	608.5225	202.36807	11
		Total	1719.9955	1493.17876	55

Descriptive Statistics – Frankfurter Sensory Analysis

	Replication	TRT	Mean	Std. Deviation	N
SPRINGY Frankfurter	1	CONTROL	7.6000	1.41185	4
		CORN100	6.4250	0.96047	4

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Sensory		CORN50	6.2500	1.64215	4
		OAT100	6.9750	0.90692	4
		OAT50	7.4250	2.17006	4
		Total	6.9350	1.43427	20
	2	CONTROL	5.7250	2.04512	4
		CORN100	7.0750	1.18708	4
		CORN50	7.0750	0.61305	4
		OAT100	5.5750	2.32719	4
		OAT50	7.6250	2.01391	4
		Total	6.6150	1.77090	20
	Total	CONTROL	6.6625	1.91082	8
		CORN100	6.7500	1.05830	8
		CORN50	6.6625	1.22933	8
		OAT100	6.2750	1.79821	8
		OAT50	7.5250	1.94110	8
		Total	6.7750	1.59884	40
CHEWY Frankfurter Sensory	1	CONTROL	3.4250	1.49750	4
		CORN100	2.5750	1.45230	4
		CORN50	3.0750	1.00789	4
		OAT100	3.2000	0.80829	4
		OAT50	2.9000	1.43295	4
		Total	3.0350	1.16677	20
	2	CONTROL	3.7500	0.77244	4
		CORN100	2.5250	0.95699	4
		CORN50	3.1500	0.95743	4
		OAT100	2.0000	1.35401	4
		OAT50	2.9750	1.32508	4
		Total	2.8800	1.14735	20
	Total	CONTROL	3.5875	1.11668	8
		CORN100	2.5500	1.13892	8
		CORN50	3.1125	0.91095	8
		OAT100	2.6000	1.21538	8

000098

		OAT50	2.9375	1.27832	8
		Total	2.9575	1.14486	40
HARDNESS Frankfurter Sensory	1	CONTROL	6.8750	1.47281	4
		CORN100	3.4000	1.45831	4
		CORN50	2.7500	0.46547	4
		OAT100	5.0250	1.96871	4
		OAT50	5.7750	1.52616	4
		Total	4.7650	2.02622	20
	2	CONTROL	5.7250	1.13835	4
		CORN100	2.8750	1.47281	4
		CORN50	5.3250	0.99457	4
		OAT100	2.3000	0.88318	4
		OAT50	4.2250	0.66521	4
		Total	4.0900	1.66414	20
	Total	CONTROL	6.3000	1.36487	8
		CORN100	3.1375	1.38558	8
		CORN50	4.0375	1.55282	8
		OAT100	3.6625	2.02903	8
		OAT50	5.0000	1.36905	8
		Total	4.4275	1.86176	40
COHESIVE Frankfurter Sensory	1	CONTROL	7.5250	1.62147	4
		CORN100	5.6750	3.13409	4
		CORN50	6.5000	1.85113	4
		OAT100	6.4750	1.98725	4
		OAT50	7.0250	1.19548	4
		Total	6.6400	1.93864	20
	2	CONTROL	6.8250	1.87150	4
		CORN100	4.7250	1.99060	4
		CORN50	7.5000	1.20000	4
		OAT100	6.6500	2.50400	4
		OAT50	6.2500	1.92267	4
		Total	6.3900	1.97001	20
	Total	CONTROL	7.1750	1.66369	8

000099

		CORN100	5.2000	2.48309	8
		CORN50	7.0000	1.53994	8
		OAT100	6.5625	2.09485	8
		OAT50	6.6375	1.53896	8
		Total	6.5150	1.93332	40
GRAINY Frankfurter Sensory	1	CONTROL	3.4750	1.92246	4
		CORN100	4.0000	2.14942	4
		CORN50	5.4250	2.11562	4
		OAT100	5.1000	1.68523	4
		OAT50	3.3000	2.26421	4
		Total	4.2600	2.01244	20
	2	CONTROL	4.1000	1.83485	4
		CORN100	4.5750	1.14419	4
		CORN50	4.0250	1.93455	4
		OAT100	4.9250	2.76330	4
		OAT50	4.2250	1.67407	4
		Total	4.3700	1.75952	20
	Total	CONTROL	3.7875	1.77155	8
		CORN100	4.2875	1.62343	8
		CORN50	4.7250	2.02043	8
		OAT100	5.0125	2.12094	8
		OAT50	3.7625	1.90858	8
		Total	4.3150	1.86665	40
OILY_MOUTH COATING Frankfurter Sensory	1	CONTROL	1.9750	1.21209	4
		CORN100	3.0250	1.43846	4
		CORN50	3.3500	1.69017	4
		OAT100	2.7750	1.44770	4
		OAT50	2.4250	1.84459	4
		Total	2.7100	1.45490	20
	2	CONTROL	2.5500	1.25033	4
		CORN100	2.4250	1.26062	4
		CORN50	2.2000	1.85652	4
		OAT100	3.2250	1.79141	4

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		OAT50	2.7250	1.84097	4
		Total	2.6250	1.48639	20
	Total	CONTROL	2.2625	1.18072	8
		CORN100	2.7250	1.29256	8
		CORN50	2.7750	1.75479	8
		OAT100	3.0000	1.52690	8
		OAT50	2.5750	1.71360	8
		Total	2.6675	1.45239	40

Gaynor, Paulette M

RECEIVED

MAR 19 2012

Division of Biotechnology and GRAS Notice Review

From: Richard Kraska [kraska@gras-associates.com]
Sent: Monday, March 19, 2012 6:32 AM
To: Gaynor, Paulette M
Cc: mcquate@gras-associates.com
Subject: Corn Fiber GRN
Attachments: FDA Transmittal Ltr Corn ZTrim 03 05 12.docx; REV. ONLY Pp. 56-57 Corn Z-Trim CGA 03 05 12 FINAL.pdf

Paulette

On March 5, we sent a GRN on corn fiber by FedEx to your attention. Hopefully this has been logged in and brought to your attention. We would like your help on a couple of matters:

1. We would of course like to have the GRN number when it is available.
2. Can you replace pages 56 and 57 with the corrected pages attached?
3. Can you confirm that the extra copy has been sent to FSIS/USDA for the review of the suitability in meat and poultry products?
4. In our discussion with Susan Carlson during the review of predecessor GRN 368, she indicated that expedited review of a revised GRN is possible. Our client would certainly appreciate this if possible.

I would be happy to discuss these matters with you. Please call me at the cell phone number below.

Thank you for your help.
Rich

Richard Kraska, Ph. D., DABT
Chief Operating Officer and Co-Founder
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March 5, 2012

Dr. Paulette Gaynor
Division of Biotechnology & GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Additive Safety & Applied Nutrition
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Corn Fiber – N-Corn Z Trim®

Dear Dr. Gaynor:

On behalf of Z Trim Holdings, Inc. of Mundelein, IL, we are submitting for FDA review the GRAS notification for Corn Fiber that is identified by the notifier as N-Corn Z Trim®. This submission reflects modifications that have been incorporated into GRN 368. Ms. Molly Harris had been involved in the coordination of the FDA review of GRN 368.

The accompanying documentation contains the specific information that addresses the safe human food uses for the subject Corn Fiber as discussed in the GRAS guidance document.

A total of four copies are provided. Some of the intended food uses include the addition of the notified substance to meat and poultry products, thereby necessitating review by USDA and the need for the fourth copy.

If additional information or clarification is needed as you and your colleagues proceed with the review, please contact me *via* telephone or email.

We look forward to your feedback.

Sincerely,

Robert S. McQuate, Ph.D.
CEO & Co-Founder
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074
541-678-5522
mcquate@gras-associates.com
www.gras-associates.com

Enclosure: GRAS Notification for Corn Fiber – N-Corn Z Trim® (four copies)

Appendix A-3

Summary of Testing Five Production Lots Versus Product Specifications

	Specification	Lot NCZT 918888	Lot NCZT 918788	Lot NCZT 918288	Lot NCZT 918388	Lot NCZT 918488	Method	Data Source
Internal COA								
Appearance	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Off-white powder with brown and black specs	Visual inspection	Appendix A-4
Odor	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless	Organoleptic	Appendix A-4
Taste	Tasteless	Tasteless	Tasteless	Tasteless	Tasteless	Tasteless	Organoleptic	Appendix A-4
Moisture	< 8.0%	6.55	6.75	6.05	6.95	7.39	Ohaus M45	Appendix A-4
Color								
L	*L>82.00*	85.29	86.43	87.68	88.01	87.32	Hunter colorflex	Appendix A-4
a	*- 0.80 – 3.00*	1.41	1.99	1.51	1.76	1.12	Hunter colorflex	Appendix A-4
b	*8.00-18.00*	14.17	14.24	12.35	11.80	14.22	Hunter colorflex	Appendix A-4
Ash	< 3.5%	2.26	0.7	1.4	0.7	0.57	CRA A-5	Appendix A-2
Total Dietary Fiber	87-92%	90.9	92.0	89.6	88.0	87.7	AOAC 985.29	Appendix A-1
Sodium	1500 mg/100g	1110	193	682	367	311	AOAC 984.27	Appendix A-2
Arsenic	< 0.2 ppm	<0.20	<0.20	<0.20	<0.20	<0.20	Atomic Absorption	Appendix A-1
Cadmium	< 0.2 ppm	<0.0500	<0.0500	<0.0500	<0.0500	<0.0500	Atomic	Appendix A-1

	Specification	Lot NCZT 918888	Lot NCZT 918788	Lot NCZT 918288	Lot NCZT 918388	Lot NCZT 918488	Method	Data Source
							Absorption	
Lead	< 0.2 ppm	<0.0500	<0.0500	<0.0500	<0.0500	<0.0500	Atomic Absorption	Appendix A-1
Mercury	< 0.2 ppm	<0.025	<0.025	<0.025	<0.025	<0.025	Atomic Absorption	Appendix A-1
APC	< 1000 cfu/g	<10	<10	190	<10	<10	AOAC 966.23	Appendix A-4
E.coli	< 10 cfu/g	<10	<10	<10	<10	<10	AOAC 991.14	Appendix A-4
Coliform	< 10 cfu/g	<10	<10	<10	<10	<10	AOAC 991.14	Appendix A-4
Yeast	< 100 cfu/g	<10	<10	<10	<10	<10	FDA BAM 8ed ch18	Appendix A-4
Mold	< 100 cfu/g	<10	<10	<10	<10	<10	FDA BAM 8ed ch18	Appendix A-4
Salmonella /25g	Negative /25g	Negative	Negative	Negative	Negative	Negative	FDA BAM 8ed ch.5	Appendix A-4

SUBMISSION END